Superior
Health Council

GOOD PRACTICES FOR THE MANAGEMENT OF REUSABLE MEDICAL DEVICES

REVISION OF THE RECOMMENDATIONS ON STERILISATION (SHC 9256 - 2017)

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.be

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Superior Health Council

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Good practices for the management of reusable medical devices Revision of the recommendations on sterilisation (SHC 9256 - 2017)

In this scientific advisory report on public health policy, the Superior Health Council of Belgium sets out good practices for healthcare facilities and central sterilization supply departments of the sterilization of medical devices.

It describes the steps that are essential for the "correct" processing of medical devices and for preserving their sterility until the point of use with a view to enhancing quality in healthcare facilities for the benefit of patients.

This version was validated by the Board on
1er februari 2023[1]

I SUMMARY

Paradoxically, it is during the medical care given to patients that the risk of contamination leading to comorbidity is greatest. Hospitals are where patients are most at risk of infection. The proper management of all reusable medical devices (MDs) is essential prior to any new use and is an important link in the control of healthcare-associated infections.

Medical and surgical diagnostic and therapeutic techniques are constantly evolving and the use of sterile medical devices is becoming increasingly important in the healthcare sector. Sterilisation techniques have also evolved. With this in mind, the Superior Health Council (SHC) felt it necessary to update the "recommendations on sterilisation techniques" published in 1993, revised in 2006 and in 2017.

The purpose of this document is to provide healthcare institutions, MD central sterilisation services (CSS) and all healthcare providers who sterilise MDs, with a good practice guide describing the essential steps for handling MDs and maintaining their sterility until they are used. In hospitals, the sterilisation of reusable medical devices is carried out in the CSS. The legislation also allows this activity to be subcontracted under certain conditions.

After a brief introduction on the requirements for the correct handling of reusable medical devices, this document describes the organisation of the CSS, the flows, the infrastructures and the necessary equipment, and recalls the hygiene rules. It is essential to master the processes by validating the different equipment (devices), the packaging and the environment

[1] The Council reserves the right to make minor typographical amendments to this document at any time. On the other hand, amendments that alter its content are automatically included in an erratum. In this case, a new version of the advisory report is issued.

before starting the activities. Periodic and "routine" inspections are necessary to ensure and maintain the quality of sterilised MDs. The traceability of the MD is an essential tool in the implementation of a quality system in the sterilisation process.

This document also discusses the importance of cleaning and disinfecting soiled MDs before sterilisation. The inspection and packaging as well as the choice of sterilisation method among the two recommended methods (saturated steam for heat-resistant MDs and vaporised hydrogen peroxide (VH_2O_2) for heat-sensitive MDs) are explained and presented.
This document formulates recommendations for the transport, storage and preservation conditions of sterile MDs.
There are chapters devoted to the loan of MDs and to the legislation on the reprocessing of single-use MDs. The outsourcing of the MD sterilisation process is also discussed.
Although there is an opinion regarding non-conventional transmissible agents (NCTAs - prions), the document includes a review of the more recent literature in the specific case of the CSS.

The publication, dissemination and implementation of these good practices will enable the different healthcare sectors to optimise practices for the management of medical devices for subsequent reuse, in the interest of everyone, especially all patients.

II CONTENTS

I SUMMARY 1

II CONTENTS 3

III INTRODUCTION AND SCOPE OF THE GOOD PRACTICES 5

1. INTRODUCTION 5
2. SCOPE 5

IV METHODOLOGY 7

V DEFINITIONS 9

VI GENERAL OBSERVATIONS 16

1. MANAGEMENT OF MDS 18
2. PRACTICAL ORGANISATION OF THE CSS 20
3. FLOW 23
4. ARCHITECTURAL DESIGN 23
5. HYGIENE 28
6. ECOLOGICAL ASPECT 31

VII PROCESS CONTROL 32

1. VALIDATION 34
2. QUALITY MANAGEMENT SYSTEM 52
3. TRACEABILITY SYSTEM 56

VIII CLEANING AND DISINFECTION 58

1. INTRODUCTION 58
2. MANAGEMENT OF SOILED/USED MDS 59
3. CLEANING AND DISINFECTION METHODS 60

IX COMPOSITION AND PACKAGING 64

1. CHECKING AND MAINTENANCE OF MDS 64
2. REPLACEMENT OF MDS 65
3. REQUIREMENTS FOR INSTRUMENT SUPPORT BASKETS 66
4. COMPOSITION OF THE SETS 67
5. CONTAMINANTS 68
6. PACKAGING AND WRAPPING 68
7. LABELLING 71

X STERILISATION PROCESS 72

1. SATURATED STEAM AND FRACTIONAL VACUUM STERILISATION 73
2. STERILISATION USING VAPORISED HYDROGEN PEROXIDE (VH_2O_2) 78
3. OTHER STERILISATION PROCESSES 83
4. SPECIAL CASE OF LINEN 83

XI STORAGE CONDITIONS FOR STERILE MD 84

1. TRANSPORT 84
2. STORAGE FACILITIES AND EQUIPMENT 85
3. CONSERVATION CONDITIONS 86

XII MD LOAN AND IN-HOUSE MANUFACTURING 87

1. LOAN OF NON-STERILE MDS 88
2. LOAN OF STERILE MD 91
3. CONSIGNMENT 93
4. TESTING 93
5. SPECIAL PRACTICES: IN-HOUSE MANUFACTURING 93

XIII SINGLE-USE MEDICAL DEVICES 94

XIV SUBCONTRACTING 95

1. LEGAL FRAMEWORK 95
2. RECOMMENDATIONS 96

XV NON-CONVENTIONAL TRANSMISSIBLE AGENTS (NCTA) 97

XVI REFERENCES 98

XVII APPENDICES 101

1. APPENDIX 1: LEGAL FRAMEWORK 101
2. APPENDIX 2: UNIT OF WORK 105
3. APPENDIX 3: USEFUL INFORMATION FOR CHECKING WATER QUALITY 109
4. APPENDIX 4: EXAMPLE STRUCTURE FOR A VALIDATION PLAN 111
5. APPENDIX 5: FMECA METHOD 112
6. APPENDIX 6: CALCULATIONS OF THE STERILISATION VALUE F_0 AND THE DISINFECTION VALUE A_0 113
7. APPENDIX 7: INDICATORS 115
8. APPENDIX 8: NON-CONVENTIONAL TRANSMISSIBLE AGENTS (NCTA - PRIONS) 117

COMPOSITION OF THE WORKING GROUP 122

III INTRODUCTION AND SCOPE OF THE GOOD PRACTICES

1. Introduction

In addition to the entry into force of various regulations such as European Regulation 2017/745 and new legal texts (e.g. Law of 22 April 2019, Royal Decrees (RDs) of 30 September 2020, 12 May 2021 and 31 May 2022), the techniques and practices of the central sterilisation services (CSSs) have evolved. With this in mind, the SHC felt it necessary to update the "Good Practices for the Sterilisation of Medical Devices" published in 2017. Previous versions of the recommendations are obsolete or incomplete as of the date of this document.

According to the Royal Decree of 26 April 2007[2], the hospital hygiene operational team must implement the guidelines and recommendations written by official bodies such as the SHC. These recommendations must be followed within a legal framework; the competent authorities, such as the FAMHP[3], base their inspections on these recommendations, which serve as a guide for accreditation.

These SHC good practices are applicable to **all healthcare providers who sterilise medical devices (MDs),** the management of healthcare institutions, the manager and staff of sterilisation departments, and the hospital pharmacy.
This guide contains the minimum requirements to be reached in CSS or for an MD sterilisation authorisation holder.

With the publication, dissemination and implementation of this guide, the SHC aims to promote a **level of quality and safety of care provided for the benefit of all patients**.

Other practices or innovative techniques than those described in these guidelines are authorised, provided these are implemented according to validated methods and prove to be equivalent in terms of quality.

These recommendations have been drafted on the basis of the regulations in force.

2. Scope

This guide concerns the management of reusable medical devices from acquisition to end of life.
The MDs concerned are:

- MDs defined according to the Medical Devices Directive (MDD) 93/42,
- MDs defined according to European Regulation 2017/745,
- reusable MDs,
- MDs used for the removal of organs and human body material for human application,
- MDs in loan equipment,
- non-sterile implantable MDs.

[2] RD 26 April 2007: *Arrêté royal modifiant l'arrêté royal du 23 octobre 1964 portant fixation des normes auxquelles les hôpitaux et leurs services doivent répondre* (i.e. Royal Decree amending the Royal Decree of 23 October 1964 defining the standards which hospitals and their departments must meet).
[3] FAMHP: Federal Agency for Medicines and Health Products

Sterilisation processes that are not applicable in hospitals, such as gamma or accelerated electron radiation and ethylene oxide sterilisation, are not discussed in this document.
Similarly, specific techniques, such as waste "autoclave", are not discussed here because the purpose of these methods is different from those performed in the CSS.

Instruments used in animal procedures, autopsies, and human cadaver sessions must be kept separate from those for clinical use and cannot be treated in the CSS.
Similarly, laboratory equipment and compound preparations are not treated in the CSS.

The treatment of heat-sensitive endoscopes and endocavity medical devices (SHC 9446, 2019), textile management in healthcare institutions (SHC 9444, 2018), and infection control during dentistry treatment (SHC 8363, 2011) were the subject of specific SHC recommendations and are still applicable. The previous versions (SHC 7848, 2006 and SHC 9256, 2017) referenced in these opinions should be superseded by this publication.

Keywords and MeSH *descriptor terms*[4]

MeSH terms*	Keywords	Sleutelwoorden	Mots clés	Schlüsselwörter
Sterilization	Sterilization	Sterilisatie	Stérilisation	Sterilisation
	Equipment on loan	Leenset	Matériel en prêt	Leihmaterial
Equipment and support	Medical device	Medisch hulpmiddel	Dispositif médical	Medizinprodukt
	Central sterilization supply department	Centrale sterilisatieafdeling	Service central de stérilisation	Zentrale Sterilisationsabteilung
	Validation	Validatie	Validation	Validierung
	CSD	CSA	SCS	ZSA
Hospitals	Hospital	Ziekenhuis	Hôpital	Krankenhaus

MeSH (Medical Subject Headings) is the NLM (National Library of Medicine) controlled vocabulary thesaurus used for indexing articles for PubMed http://www.ncbi.nlm.nih.gov/mesh.

IV METHODOLOGY

After analysing the request, the Board and working group Chair identified the necessary areas of expertise. An *ad hoc* working group was then set up which included experts in hospital pharmacy, nursing practice, hospital hygiene practice, sterilisation, microbiology and prions - NCTA[5] . The experts of this working group provided a general and an ad hoc declaration of interests and the Committee on Deontology assessed the potential risk of conflicts of interest. Representatives of the Federal Agency for Medicines and Health Products (FAMHP) were also consulted.

This advisory report is based on the regulations in force (appendix 1), the scientific literature, reports from national and international organisations competent in this field (peer-reviewed), as well as on the opinion of the experts.

Once the advisory report had been approved by the working group, it was ultimately validated by the Board.

Abbreviations and symbols

ADR	Accord for dangerous goods by roads
AKI	*Arbeitskreis Instrumentenaufbereitung*
ANSM	*Agence nationale de sécurité du médicament et des produits de santé* - France
ASTER	*Association Belge Francophone de stérilisation des dispositifs médicaux* - Belgium
$CaCO_3$	Limestone
CAPA	Corrective action and preventive action
CFU	Colony-forming unit
CJD	Creutzfeldt-Jakob disease
CSS	Central sterilisation services
DIN	*Deutsches Institut für Normung*
EC	European Commission
ECDC	European Centre for Disease Prevention and Control

[4] The Council wishes to clarify that the MeSH terms and keywords are used for referencing purposes as well as to provide an easy definition of the scope of the advisory report. For more information, see the section entitled "methodology".

[5] NCTA: Non-conventional transmissible agents

EU	European Union
FAMHP	Federal Agency for Medicines and Health Products
GDPR	General data protection regulation
H_2O_2	Hydrogen peroxide
HAS	Hydroalcoholic solution
HEPA	High Efficiency Particulate Air
HHC	Hospital Hygiene Committee
HR	Human resources
IFU	Instruction for use
IMS	Independant monitoring system
IQ	Installation qualification
ISO	International Organization for Standardization
KPI	Key Performance Indicators
MD	Medical devices
MDD	Medical devices directive
MDR	Medical device regulation
MEC	Medical equipment committee
MPE	Maximum permissible error
NCTA	Non-conventional transmissible agents
OQ	Operational qualification
P&ID	Piping & Instrumentation diagram
PCD	Process Challenge device
PPE	Personal protective equipment
PQ	Performance qualification
PrPsc	Pathological prion protein
QMS	Quality Management System
RD	Royal Decree
RFID	Radio frequency identification
RO	Reversed osmose
RQ	Requalification
RT-QuIC	Real Time Quaking Induced Conversion
SAL	Sterility assurance level
SBS	Sterile barrier system
SHC	Superior Health Council
SLA	Service Level Agreement
TSE	Transmissible spongiform encephalopathies
UDI	Unique device identifier
VH_2O_2	Vaporised hydrogen peroxide
VSZ	Vereniging *S*terilisatie in het Ziekenhuis - Belgium
WD	Washer-disinfectors

V DEFINITIONS

Accuracy
The closeness of agreement between a test result and the accepted reference value (ISO 5725-1: 1994).

Adjustment (of a measuring system)
Set of operations performed on a measuring system so that it provides prescribed indications that correspond to given values of the quantities to be measured (ISO/IEC Guide 99: 2007).

Note 1: various types of adjustment of a measuring system are zero adjustment, offset adjustment, range adjustment (also called gain adjustment).
Note 2: the adjustment of a measuring system should not be confused with its calibration, which is a prerequisite for adjustment.
Note 3: the system usually requires recalibration after an adjustment of a measuring system.

Batch number
Designation, in numeric or alphanumeric form, to identify and track a set of MDs/sets that share certain production characteristics (time and date of production, identification code, etc.).

Bioburden
Biological load consisting of all the viable microorganisms contained in a device or on a surface.

Biofilm
Community of microorganisms which stick together, and also to a surface, characterised by the secretion of an adhesive, protective matrix. Due to specific phenotypic expression, the microorganisms are more resistant to external conditions. This is a natural behaviour observed in colonisation and adaptation to a hostile environment.

Calibration[6]
Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication (ISO/IEC Guide 99: 2007).
The result of a calibration may be recorded in a document, also called a calibration certificate or calibration report.

Note on the use of the French terms Etalonnage vs Calibration vs Calibrage
The International Vocabulary of Metrology in French only recognises the term 'Etalonnage'.
"Calibration" is the English equivalent of "Etalonnage". In French, it is unfortunately used too often instead of 'étalonnage'.
The term 'calibrage' exists in French and has several definitions, but none of them comes close to the concept of calibration. Unfortunately, it is also used incorrectly here, even in certain standards, such as EN 285.

[6] In French, the terms "calibrage" and "calibration" should not be used in documents because they are not part of the VIM (International Vocabulary of Metrology).

Central Sterilisation Service (CSS)
Medical and technical department of the care institution where the sterilisation activities are centralised. It is autonomous, independent of the operating room, and houses all the necessary resources and skills.

Cleaning
Removal of contamination from an item to the extent necessary for further processing or for intended use.

Consignment
Long-term provision of MDs by the supplier.

Contaminant
Any biological or chemical agent, foreign material or other substance not intentionally added to the MDs that may compromise safety or sterility.

Customer
Department that benefits from CSS activity (operating room, care unit, users).

Decontamination
Action to remove all visible dirt adhering to the devices and reduce the number of particles and micro-organisms.

Disinfection
Operation with a momentary result that reduces the number of microorganisms in or on an inanimate matrix, obtained via the irreversible action on their structure or metabolism, at a level deemed appropriate according to a given objective. The result of the operation is limited to the microorganisms present at the time of the operation.

Equipment on loan (set on loan)
Provision of MDs by the supplier for a single medical procedure.

Equipment qualification
The final round of inspections and tests to ensure that the critical requirements necessary for product quality are met and that the documents and procedures necessary to operate and maintain the system are in place (Agalloco, 2022).

F_0 sterilising value
Measure of microbiological lethality delivered by a moist heat sterilisation process expressed in terms of the equivalent time, in minutes, at a temperature of 121,1°C with reference to microorganisms with a z value of 10 (ISO 11139: 2018).
As the F_0 value is calculated from the measured temperature, it is particularly useful to compare the sterilising effect that two sterilisation cycles with sometimes different temperature profiles can have on the same load.

Identification code
Unique numeric or alphanumeric code for identifying an MD/set.

Inactivation
Treatment that reduces the infectivity of the treated MD and treatment fluids.

Individual care provider
Person licensed to provide certain health care services (provides health care).

Installation Qualification (IQ)
Process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification (ISO 11139: 2018).

Key performance indicators (KPIs)
This indicator is quantified and makes it possible to monitor the effectiveness of an action in relation to defined objectives.

Large/Small steriliser
Steam steriliser designed to accommodate at least one sterilisation module or having a chamber volume of at least 60 litres (large: EN 285) or less than 60 litres (small: ISO 13060).

Load
Product, equipment, or materials to be processed together within an operating cycle (ISO 11139: 2018).

Loan for a test
Provision of MDs by the supplier for the duration of a test; it is treated as a short-term consignment.

Management of an MD
Cleaning, disinfection and sterilisation of the MD, depending on its level of criticality, with a view to its reuse.

Maximum permissible error (MPE) or limit of error
Extreme value of measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system (JCGM 200: 2012).
Example: a temperature measuring system with an MPE of ± 0.2°C.

Medical device (MD)
Any instrument, apparatus, implement, machine, appliance, implant, reagent or other article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognostic, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point (MDR 2017/745).

MDs not to be resterilised
MDs that must not be resterilised (ISO 15223-1: 2021).

Measurement result
Result of measurement (JCGM 200: 2012).

> Note: A measurement result is generally expressed as a single measured quantity value and measurement uncertainty. If the measurement uncertainty is considered to be negligible for some purpose, the measurement result may be expressed as a single measured quantity value. In many fields, this is the common way of expressing a measurement result.

Measuring chain
Series of elements of a measuring instrument or measuring system, which constitutes the path of the measurement signal from the input (quantity subject to measurement) to the output (the result of the measurement) (ISO 11139: 2018).

Non-condensable gas
Air and/or other gas which will not liquefy under the conditions of a saturated steam process.

Operational Qualification (OQ)
Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures (ISO 11139: 2018).

Packaging system
Combination of a sterile barrier system (SBS) and protective packaging (ISO 11607).

Parametric release
Declaration that a product is sterile based on records demonstrating that the process parameters were delivered within specified tolerances (ISO TS/11139: 2006, definition 2.29). It can only be achieved if all the process parameters are specified, controlled and directly monitored. Records of the process parameters must be kept (ISO 14937: 2009, 11.2).

Performance Qualification (PQ)
Process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements (ISO 11139: 2018).

Process
Activity that transforms input elements into output elements (product). The output elements of one process often form the input elements of the next process.

Process challenge device (PCD)
Instrument or article providing a defined resistance to a cleaning, disinfection or sterilisation process and intended to evaluate the effectiveness of the process.

Qualification
Activities undertaken to demonstrate that utilities, equipment, and methods or modes are suitable for their intended use and perform properly (ISO 11139: 2018).

Reference load
Specified load(s) created to represent difficult combinations of MD to be cleaned, disinfected or sterilised (ISO 17665-1: 2006).

Repeatability conditions
Conditions where independent test results are obtained by the same method on identical test loads, by the same operator, using the same equipment and within short intervals of time (based on ISO 5725-1: 1994).

Reprocessing
A process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device (MDR 2017/745, definition 39). This term is only used in the MDR in the context of single-use MDs (Art 17).

Reproducibility conditions
Conditions where test results are obtained with the same method on identical test loads, with different operators using different equipment (based on ISO 5725-1: 1994).

Requalification (RQ)
Repetition of part or all of validation for the purpose of confirming the continued acceptability of a specified process (ISO 11139: 2018).

Routine test
Technical operation performed periodically to establish that the operating performance of the equipment or process remains within the limits established during validation (ISO 11139: 2018).

Serial number
Unique designation in numeric or alphanumeric form that is assigned to an MD/set in a series to identify it. It is temporary and new for each production cycle.

Single-use device
Any device intended to be used only once (one use ISO 15223-1: 2021) or on an individual during a single procedure (MDR 2017/745).

Sterility assurance level (SAL)
Probability of a single viable microorganism occurring on an item after sterilisation.

> Note 1 to entry: It is expressed as the negative exponent to the base 10 (ISO 11139: 2018). It must be 10^{-6} for an object designated as "sterile".

Service-level agreement (SLA)
A document that defines the quality of a service between a service provider and a customer. In other words, these are contract-based clauses that define the precise objectives and level of service a customer wants from the supplier and set out responsibilities.

Sterile
Free from viable microorganisms (SAL 10^{-6}) (ISO/TS 11139: 2006, definition 2.43).

Sterile barrier system
Minimum package that minimises the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use (ISO 11607).

Sterilisation
Validated process used to render product free from viable microorganisms.

> Note: In a sterilisation process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero. (ISO/TS 11139: 2006 paragraph 2.47).

According to the Royal Decree of 30 September 2020 (Article 2, 4), the term "sterilisation" describes the set of processes aimed at the destruction or irreversible inactivation of all living microorganisms present in any kind and in any form in or on perfectly cleaned medical devices.

Supplier
Entity from which the MDs are ordered.

Traceability
Implementation of a system for tracking the MD at all stages of its life cycle and proactive introduction of the desired processes.

Unique device identifier (UDI)
The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market (MDR 2017/745).

Validation
Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications (ISO 17665-1: 2006).

Value "A"/"A_0" (disinfection value)
Equivalent time in seconds at 80°C to produce a given disinfection effect. When the specified temperature is 80°C and the Z value is 10, the term "A_0" is used (see Appendix 6).

Washing
Removal of contaminants from surfaces by means of an aqueous fluid (ISO 11139: 2018).

VI GENERAL OBSERVATIONS

1. Management of MDs

2. Practical organisation of the CSS
- 2.1. Legal framework
- 2.2. Centralization of sterilisation activities
- 2.3. Human resources

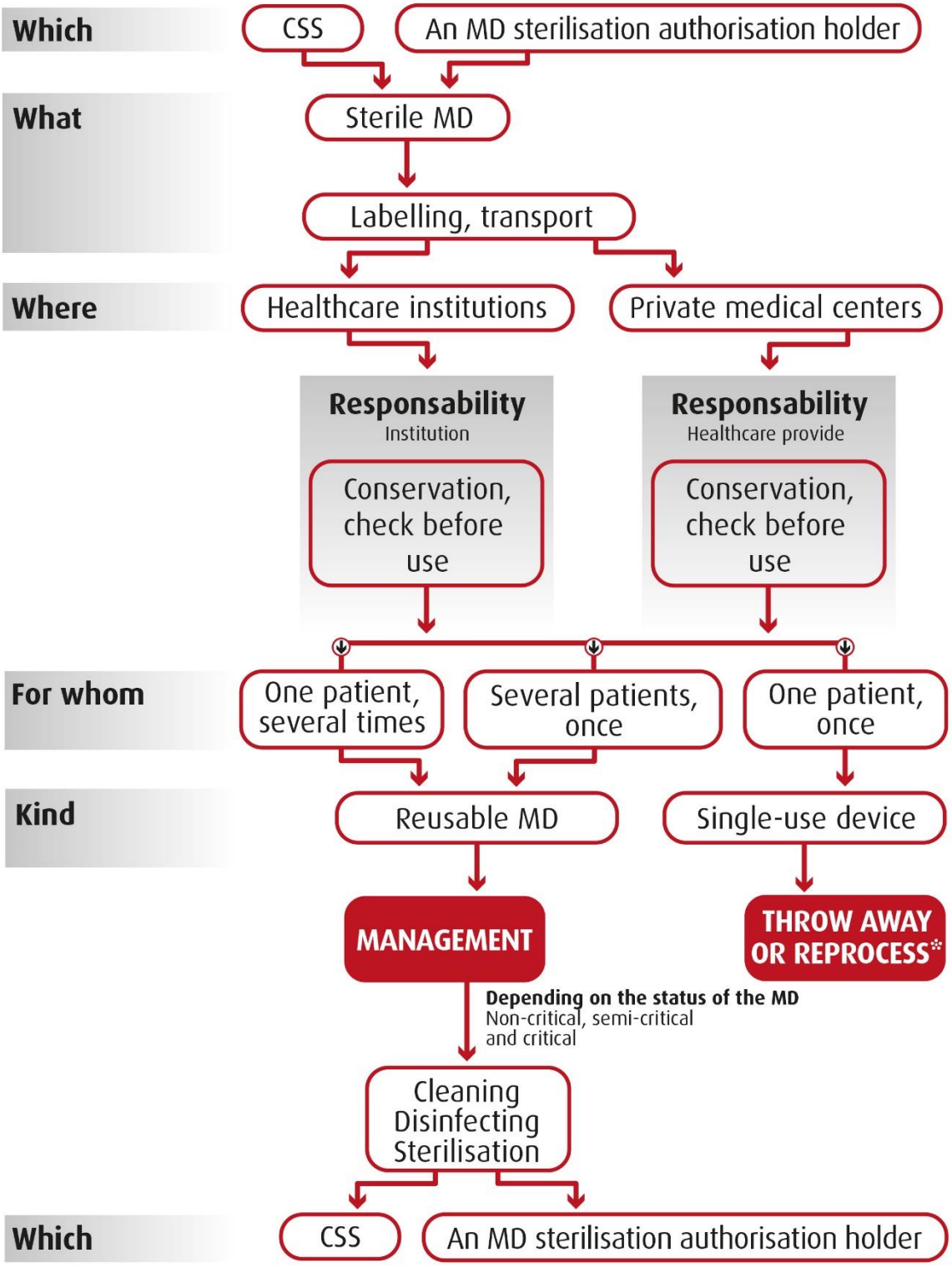
3. Flow

4. Architectural design
- 4.1. Construction conditions
- 4.2. Functional and spatial conditions
- 4.3. Air checking
- 4.4. Water quality
  - 4.4.1. Drinking water
  - 4.4.2. Softened water
  - 4.4.3. Chilled water
  - 4.4.4. Hot water
  - 4.4.5. Osmosis water
- 4.5. Minimum equipment
- 4.6. Maintenance of the premises

5. Hygiene

6. Ecological aspect

Diagram 1: Sterile MD circuit



* according to art.17 MDR 2017/745

1. Management of MDs

"Management of an MD" means the cleaning, disinfection and sterilisation of the MD, depending on its level of criticality, with a view to its reuse.

The CSS deals only with MDs as described in point 2, Chapter III.

The use of reusable MDs implies the application of documented treatment procedures.
MDs can be subdivided according to their use and the risk of transmission of infectious agents.

Spaulding's historical classification (CDC, 2008) provides the common thread for treatment procedures to be applied and defines three critical levels for equipment disinfection. Each level requires appropriate microbiological cleanliness, which can be achieved by different levels of disinfection combined or not combined with sterilisation:

- Critical device: a device is considered critical if it presents a risk of infection, if it is contaminated with a microorganism. Items which penetrate sterile tissue or the cardiovascular system must be **sterilised**.
- Semi-critical device: a device is considered semi-critical if it comes into contact with mucous membranes or damaged skin. The items should be free from microorganisms, but a small number of spores is authorised. Semi-critical items require at least high-level disinfection (with chemical disinfectants or physical methods).
- Non-critical device: a device is considered non-critical if it comes into contact with intact skin. Non-critical items may be disinfected with low-level disinfectants.

Table 1: Spaulding classification

Use of the device	Classification	Risk level	Processing required
Insertion into the vascular system or sterile tissue	Critical	High risk of infection	Sterilisation
Contact with mucous membranes or superficially damaged skin	Semi-critical	Moderate to high risk of infection	High-level disinfection
Contact with patient's intact skin or no contact with the patient	Non-critical	Low risk of infection	Low-level disinfection

Objectives

Cleaning is the first step that aims to eliminate visible and invisible contaminants present on the MD.

Disinfection aims to reduce the bioburden on the object. Disinfection is defined as a reduction in the number of microorganisms in or on an inanimate matrix, obtained via the irreversible action on their structure or metabolism, at a level deemed appropriate according to a given objective.
The levels of disinfection correspond to the efficacy on the different microorganisms.

Sterilisation involves a chain of processes leading to the sterility of the treated MD, defined by the absence of viable microorganisms on this MD. The aim of sterilisation is therefore to destroy or irreversibly inactivate microorganisms present in or on an item such that the likelihood of there being no more than one viable microorganism per million treated units is achieved (10^{-6}) (European Pharmacopoeia 8.0, section 5.1.1.), and this state is maintained up to use of the MD.

Cleaning, disinfection and sterilisation can be done by physical and/or chemical means.

Sterilisation can be achieved using certain disinfectants, at higher concentrations and longer contact times (chemical sterilisation).

Table 2: Efficacy of the procedure according to the type of microorganism concerned

	Vegetative bacteria	**Mycobacteria**	**Fungi**	**Virus**	**Spores**
Sterilisation	Yes	Yes	Yes	Yes	Yes
High-level disinfection	Yes	Yes	Yes	Yes	Partially
Low-level disinfection	Majority	-	Some	Some	-

As it is not possible to verify the sterility of MDs before use with tests on the end product, it is essential to **validate the processes and devices** and **continue to monitor** all processes through checks. Prior and correctly validated cleaning and disinfection procedures are essential to ensure effective sterilisation.

The following aspects must be taken into consideration when drafting recommendations for MD sterilisation techniques:

- human resources,
- the use of an appropriate infrastructure and adequate ambient conditions (ventilation, humidity, pressure, etc.),
- the use of reusable MDs,
- compliance with the required hygiene precautions to reduce the bioburden before sterilisation,
- compliance with the hygiene precautions required to guarantee the safety of the staff,
- the implementation of validated methods at every critical stage of MD management,
- monitoring of the environment,
- the guarantee of good storage and conservation conditions,
- the use of a quality assurance and traceability system for MDs.

2. Practical organisation of the CSS

2.1. Legal framework

The RD of 23 October 1964 establishing the standards that hospitals and their services must meet (special standards for diagnostic and surgical services: Index C. Organisational Standards 2°) states that:
"The sterilisation of instruments and bandages must be carried out impeccably, by means of reliable installations in perfect working order. Certificates of operation must be made available to the inspection authorities.

The service must have competent staff available at all times for the operating room and for sterilisation."

The RD of 15 December 1978 sets special standards for university hospitals and services (Appendix 5 of Chapter XI) and cites:
"The hospital must have a central sterilisation service on site. This service shall maintain, sterilise and distribute material for all hospital services. If the hospital uses an external sterilisation service, it is nevertheless required to have limited and central sterilisation equipment including autoclave. This minimum equipment must be kept ready for use to be able to cope with unforeseen situations at all times.

All sterilisation equipment must be concentrated in the central sterilisation service.

The central sterilisation service has a dirty, a clean and a sterile area respectively.

The sterilisation systems used must be equipped with the required monitoring and recording equipment that records the essential data of the sterilisation process.

The monitoring of day-to-day activities is the responsibility of a hospital doctor or hospital pharmacist, designated for this purpose.

Day-to-day activities are performed under the direction and monitoring of a nurse, designated by name.
A nurse must be present during each sterilisation operation."

The RD of 18 June 1990 establishing the list of technical services of the nursing profession and the list of acts that a doctor can entrust to the nursing profession, as well as the modalities of execution relating to these services and acts and the conditions of qualification that the nursing profession must meet, includes in its Annex I[7] the:

- *"Monitoring of the preparation of the material to be sterilised and the sterilisation procedure."*

[7] Annex I. - List of technical services of the art of nursing that can be performed by practising nurses established in application of Article (21d, §3 - RD of 7 October 2002, Art. 3 - BOG of 7 November 2002, p. 50587) of the RD no. 78 of 10 November 1967), list of acts B1, 1.8 - specific techniques

The RD of 4 March 1991 establishing the standards that a hospital pharmacy must meet to be certified (Chapter III, Article 12) states that:
"The hospital pharmacist must ensure the quality of daily CSS activities by:

1° providing advice on the choice of equipment and sterilisation methods;
2° validating sterilisation procedures;
3° supervising the various stages preceding sterilisation: cleaning, disinfection and packaging of the material to be sterilised;
4° supervising the storage arrangements for sterile material."

The RD of 30 September 2020 on the preparation and delivery of drugs and the use and distribution of medical devices in healthcare facilities states in its Articles 17 and 20 (amended by the RD of 31 May 2022) that:
*"The sterilisation of medical devices is carried out within the institution, under the responsibility of the hospital pharmacist, except in the cases referred to in Art. 22 (*subcontracting of MD sterilisation*) and Art. 23* (shared hospital function by virtue of a formalised collaboration agreement between care institutions).

The sterilisation of medical devices must take place in accordance with the principles of the Guidelines for the Sterilisation of Medical Devices, as listed in Annex IIa and IIb."

2.2. Centralisation of sterilisation activities

The **management** of sterilisation-related activities in the hospital should be **centralised** and take place in the CSS. Sterilisation activities can be decentralised, particularly in the case of multi-site institutions[8], but they must always be under centralised management.
The processes must be performed according to reproducible, validated and standardised protocols for all sites.

The CSS is an autonomous medical and technical service that is independent of the operating room and houses all the necessary resources and skills. It is located so that the logistics processes are optimised and organised in such a way as to clearly separate contaminated MDs from sterile MDs.

This centralisation guarantees the standardisation of procedures and more efficient management by and under the supervision of qualified and constantly trained staff.

A sterilisation process in accordance with good practice takes a minimum of five hours.

2.3. Human resources

The **hospital pharmacist**, appointed as the person in charge of the CSS, guarantees the quality of the daily activities in the CSS, in accordance with the RD of 4 March 1991 and the RD of 30 September 2020.
No operational changes can be made without his prior consent.

[8] Law of 10 July 2008

In this document, the term "nurse" corresponds to the term defined in current Belgian law.

A **head nurse** will be designated to organise the activities of the team of nurses and sterilisation agents and ensure the day-to-day operation and coordination of the CSS. Specific training in CSS management, recognised by the competent authority, is mandatory (RD of 18 June 1990; RD of 15 December 1978).

CSS nurses must be specialised in MD management.

Technicians specialised in MD management must have at least a secondary vocational education diploma and a certificate attesting to specific training in MD sterilisation recognised by the competent authority.

Ongoing training is essential, particularly when implementing new or modified processes.

Each sterilisation process requires supervision by a specialised nurse.

The release of sterile MDs is subject to a procedure. In the event of doubt, only the head of the service and/or the hospital pharmacist can make a decision on their release. If the above-mentioned person is absent, the MD will be placed in quarantine or undergo a new sterilisation process.

The number of CSS staff should be commensurate with the number and nature of the hospital's medical activity and the quantity of MDs required for that activity.
To assess needs and monitor the service's activity, the CSS manager can use the work unit calculation (example in Appendix 2). This calculation method takes into account the complexity and number of MDs that make up the instrument sets. The table for calculating activity, costs and staffing is available on the website of the professional associations ASTER[9] and VSZ[10].

The service's working hours are adapted to the workload, depending on hospital activity and the availability of trained staff.

The assignment of technical staff to maintenance and repair work on the devices in the CSS is recommended. This technical staff must have received specific training on CSS equipment from the manufacturers.

An IT and traceability manager must be assigned to the CSS; they will be trained to implement, maintain and secure IT programmes and equipment.

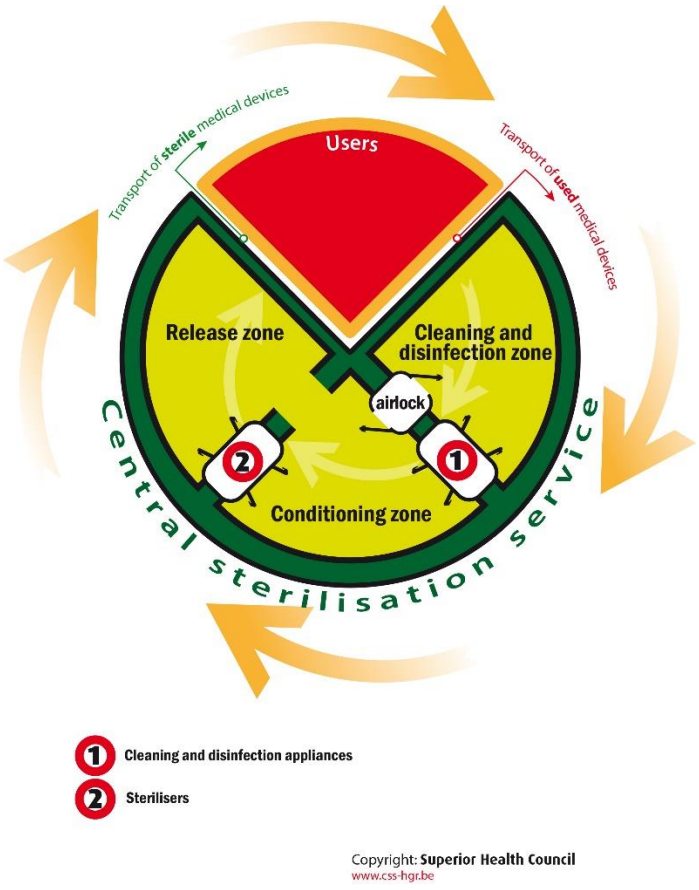
[9] ASTER: Belgian French-speaking association for the sterilisation of medical devices
[10] VSZ: Belgische Vereniging Sterilisatie in het Ziekenhuis

3. Flow

The layout, equipment and organisation of the CSS must take into account a number of rules in order to avoid the intermingling of the different flows, the contamination of the working environment, the staff and the products. To do this, it is essential to:

- establish separate areas with specific access procedures and a clear separation between soiled, clean and sterile MDs,
- ensure compliance with the principle of forward motion for the MDs (soiled, clean, sterile),
- limit access to authorised persons only,
- enforce basic hygiene rules (such as hand hygiene, general prevention rules and dress code, etc.) for staff and visitors.

Figure 2: Description of the MD flow in the hospital



4. Architectural design

The surface area of the service allows the separation of the rooms and the principle of forward movement (flow) with the appropriate equipment and the essential supplies (consumables). The required surface area must be adapted to the activities carried out, the necessary equipment and the organisation of the work. According to the CSS, a minimum total surface area of 250 m² is necessary, including the three production areas, the technical area and the administrative section.

Its architectural design provides for a subdivision of the production area into three physically distinct zones[11]:

- the washing and disinfection area: sorting, washing and disinfection of MDs and transport systems,
- the packaging area: check, assembly, packaging and sterilisation,
- the release area: release check, *cooldown*, storage, sorting and transport.

For staff, the washing and disinfection area on the one hand, and the packaging and release areas on the other hand, are two separate entities.
Staff access is via a specific airlock for the washing and disinfection area and for the packaging and release area.

4.1. Construction conditions

The floor, wall and ceiling finishes must:

- be smooth (non-porous), seamless and sealed,
- ensure seamless transition,
- be cleanable and disinfectable,
- be resistant to the high moisture content and high temperature inherent in the processes.

Ceiling: HEPA filters and extraction vents must be positioned correctly. Additional extraction is provided near the washer-disinfectors (WD) equipment (aerosols) and sterilisers.

The doors close automatically (essential for air control), and should preferably open via sensor control (foot, arm, etc.).

The walls are lined with protectors/bumpers to prevent damage.

The windows cannot be opened.
The windows and steel structures are placed in the exterior façade to avoid condensation and/or thermal bridges.

The technical areas of the facility present a potential risk of contamination and are best entered outside of production for maintenance and repair.

4.2. Functional and spatial conditions

Temperature: a temperature range of between 18°C and 22°C is recommended, taking into account the nature of the work, comfort and the equipment present.

Relative humidity: a range of 35% minimum to 65% maximum is recommended (ISO 14644).

[11] The names of the zones in these recommendations have been adapted from the 1978 Royal Decree.

Lighting: daylight promotes good visual checks and has a positive effect on employees. If artificial light is used, the Lux values are described in standard ISO 12464, which sets the objective of finding a balance between light and colour.

Noise: the design, production and presence of machinery can result in high noise levels. A **maximum** daily exposure of 80dB applies as an upper limit (Workplace Wellbeing Codex).

4.3. Air checking

In Belgium, the characteristics of ISO class 8[12] at rest in the packaging area with their periodic and continuous checks must be respected in accordance with the RD of 30 September 2020 (Annex 2A). Periodic checks include air purity (particle measurement) and filter efficiency (see also section on validation).

It is recommended that temperature, pressure (pressure difference between areas) and humidity in the packaging and release area be continuously monitored via a building management system.
The results of these measurements must be continuously available to the CSS manager.

To achieve ISO class 8, the appropriate replacement of the air treated by a HEPA filter is required[13]. To guarantee high pressure of at least 15 Pascals (NF S 90-351 standard), an airlock must be provided for the MD between the washing and disinfection area on the one hand and the packaging area on the other. Personnel must enter via an airlock. The two doors of the passage hatch and the airlock cannot be opened at the same time.

Ideally, the different pressures within the CSS will be distributed as follows:

- maximum high pressure (30 Pa) in the MD packaging and release areas,
- high pressure (15 Pa), storage area and in the airlocks,
- atmospheric pressure in the reception and sorting area, washing area, changing rooms and adjacent areas.

If linen is to be sterilised, it must be packaged in a separate room from the MD packaging room to prevent any particles from entering. For the same reason, all the packaging (cartons, etc.) of consumables must be removed before entering the packaging area.

The air from the washing and disinfection area can only be recovered if it is treated. If not, it must be evacuated to the outside. It must be replaced at a minimum of 6 volumes/hour.

The above requirements only make sense if and when strict hygiene procedures are followed (cleaning instructions, hand hygiene, dress code, etc.).

[12] ISO Class 8 defines the maximum permissible concentrations (particles/m³ of air) of particles equal to or greater than 3,520,000 for 0.5 µm; 832,000 for 1 µm and 29,300 for 5 µm.
[13] HEPA: High Efficiency Particulate Air

4.4. Water quality

There are many different water qualities, each with its own specific requirements.
In the CSS, there are different elements to take into account in terms of water quality: the presence of microorganisms, limestone ($CaCO_3$), chlorides, silicates; as well as a number of other elements.

- Limestone is responsible for the appearance of whitish residues on the MDs and inside WD.
- Silicates and chlorides can corrode metal alloys including stainless steel, especially at the high temperatures encountered during the sterilisation process.

Several units of measurement exist to determine water quality:

- °fH ($CaCO_3$ content) or °dH (CaO content) to estimate the hardness of the water,
- conductivity, expressed in microsiemens per centimetre (µS/cm), allowing the presence of mineral salts to be quantified,
- the presence of dry residues (mineral salts) using the unit mg/l (or mmol/l),
- the presence of microorganisms by counting colonies per litre (CFU[14]/l),
- the acidity of the water defined using the pH scale.

Only the types of water encountered in the CSS will be discussed here. The definition of the water types relates to the composition of the water, as well as the method of production.

The SHC draws the attention of users to the fact that water is a precious resource and that the CSS must think of possible ways to limit its consumption.

4.4.1. Drinking water

This is defined by a European directive which determines the maximum limits allowed in water intended for human consumption. These limits are in principle respected for distribution water (Annex 1 of Directive 98/83/EC).

The microbiological aspects that may be monitored are listed in the table in Annex 3.

4.4.2. Softened water

Calcium and magnesium are mainly removed from softened water. The softened water is produced by the hospital or ideally in a specific water facility at the CSS. In the latter case, the installation must provide for the continuity of softened water production.
Softened water is mainly used to supply the vacuum pumps of the autoclaves for cooling, the washing phase of the washers-disinfectors and the cart-washers, as well as the ultrasound devices and the sink taps in the washing and disinfection area of the CSS.
The characteristics of this water must meet the requirements described in Table 3.

There is no European standard describing the limits for defining water hardness.

[14] CFU Colony-forming unit

In general, water with a calcium carbonate concentration of less than 50 mg/L (5°fH) is considered to be very soft water and water with a calcium carbonate concentration of more than 350 mg/L (35°fH) is considered to be very hard water.

Molar mass of $CaCO_3$: 100g/mol.
1°fH (French degree) = 10 mg $CaCO_3$ (calcium carbonate) per litre.
1°dH (German degree) = 10 mg of CaO (calcium oxide) per litre or 17.9 mg/l of $CaCO_3$.

Table 3: Water hardness

°fH	°dH	Water category
from 5 to 15	from 3 to 8	Soft water
from 15 to 25	from 8 to 14	Medium hard water
from 25 to 35	from 14 to 20	Hard water
more than 35	more than 20	Very hard water

The AKI[15] recommends a water hardness of 3°dH or approximately 5°fH.
The various manufacturers of CSS and MD equipment communicate the recommended hardness levels for the optimal use of their equipment and MD processing.

4.4.3. Chilled water

To supply certain machines or devices, it is sometimes necessary to use cooled water to limit wear and tear (vacuum pump cooling) or to produce cooled air. Some CSSs therefore have chilled water supplies.
In this case, each steriliser must be supplied directly with chilled water; therefore, the sterilisers cannot be supplied in series.
The water temperature is set by the steriliser manufacturer.

4.4.4. Hot water

Hot water is softened to a maximum temperature of 55°C.

4.4.5. Osmosis water

Osmosis water is very pure water with a very low dry residue content. It is obtained by reverse osmosis, which is a particular filtration technique using membranes and ion exchange resins. This is generally the preferred technique for producing high quality water in hospitals as it allows rapid production in large quantities.
The requirements may differ depending on the purpose. The appendices to standard EN 285 include the admissible values for the supply of the steam generator. The ISO/TS 17665-2 standard contains the permitted values for condensates. This aspect will not be discussed in these recommendations.

Note: Appendix 3 contains tables of suggested maximum values for contaminants in the feed water of a dedicated steam generator.

[15] AKI: *Arbeitskreis Instrumentenaufbereitung* - Über uns | AKI Arbeitskreis Instrumentenaufbereitung (a-k-i.org/en)

4.5. Minimum equipment

The CSS must have sufficient devices to process the used MDs within the time frame agreed upon in the SLA (*Service Level Agreement)* with the customers.

- washer-disinfector with automatic double door between the washing and disinfection area and the packaging area,
- automatic double door steriliser between the packaging area and the release area,
- and related equipment (ultrasound, welding machines, drying cabinet, etc.).

In addition, automatic cleaning and disinfection devices will be provided for reusable containers and transport carts.
During the construction/renovation of a new CSS, the activity peaks of the different MD user services will be taken into consideration to calculate the amount of equipment to be installed and the minimum surface area to be provided.
The capacity must be large enough to ensure continuity of processes, taking into account maintenance, outages and activity.

4.6. Maintenance of the premises

The premises are maintained daily in accordance with the procedure validated by the Hospital Hygiene Committee (HHC). The CSS manager must perform surface cleaning checks in collaboration with the hospital hygiene team. It is recommended that an SLA be drafted regarding the maintenance agreements for the different areas of the CSS.

5. Hygiene

The hygiene rules set out by the "hospital hygiene" service (such as hand hygiene, dress code, use of personal protective equipment, access to premises, etc.) must be respected by CSS staff, technical staff, maintenance staff and visitors. Basic hand hygiene requirements must be met at all times (wrists, hands, forearms without jewellery, nails: short, clean, no nail polish or artificial nails) (SHC 9344, 2018).

All CSS staff have been trained in proper hand hygiene techniques. Visual reminders of the correct hand washing and sanitising method are present. The CSS is equipped with the necessary facilities for hand washing and disinfection with hydroalcoholic solution (HAS). Hand wash stations with HAS accessories must be installed at CSS entrances and exits, including staff areas.

Each hand wash station is equipped with a mixer tap, liquid soap and paper towels, including a bin without a lid or with a foot pedal for the disposal of used paper towels. The mixing valve is equipped with foot, elbow, knee or electronic eye control. HAS is available in the packaging area and in the release area (WHO, 2016; Qualicor Europe Qmentum international, 2021).

The basic dress code for the different CSS areas consists of a closed suit[16] provided by the facility, a disposable cap that fully covers the hair and sturdy, fully enclosed shoes with a non-slip sole. These shoes must be easy to clean and disinfect and this must take place on a periodic basis (WHO, 2016; SVN/VDSMH 2017).

Additional personal protective equipment (PPE) is required in the cleaning and disinfection area and in the release area. Staff must be trained in its proper use and in the correct procedure for removing PPE when leaving the cleaning and disinfecting area. The table below summarises the recommended PPE (WHO 2016; APSIC, 2017; SVN/VDSMH, 2017; HSE, 2014).

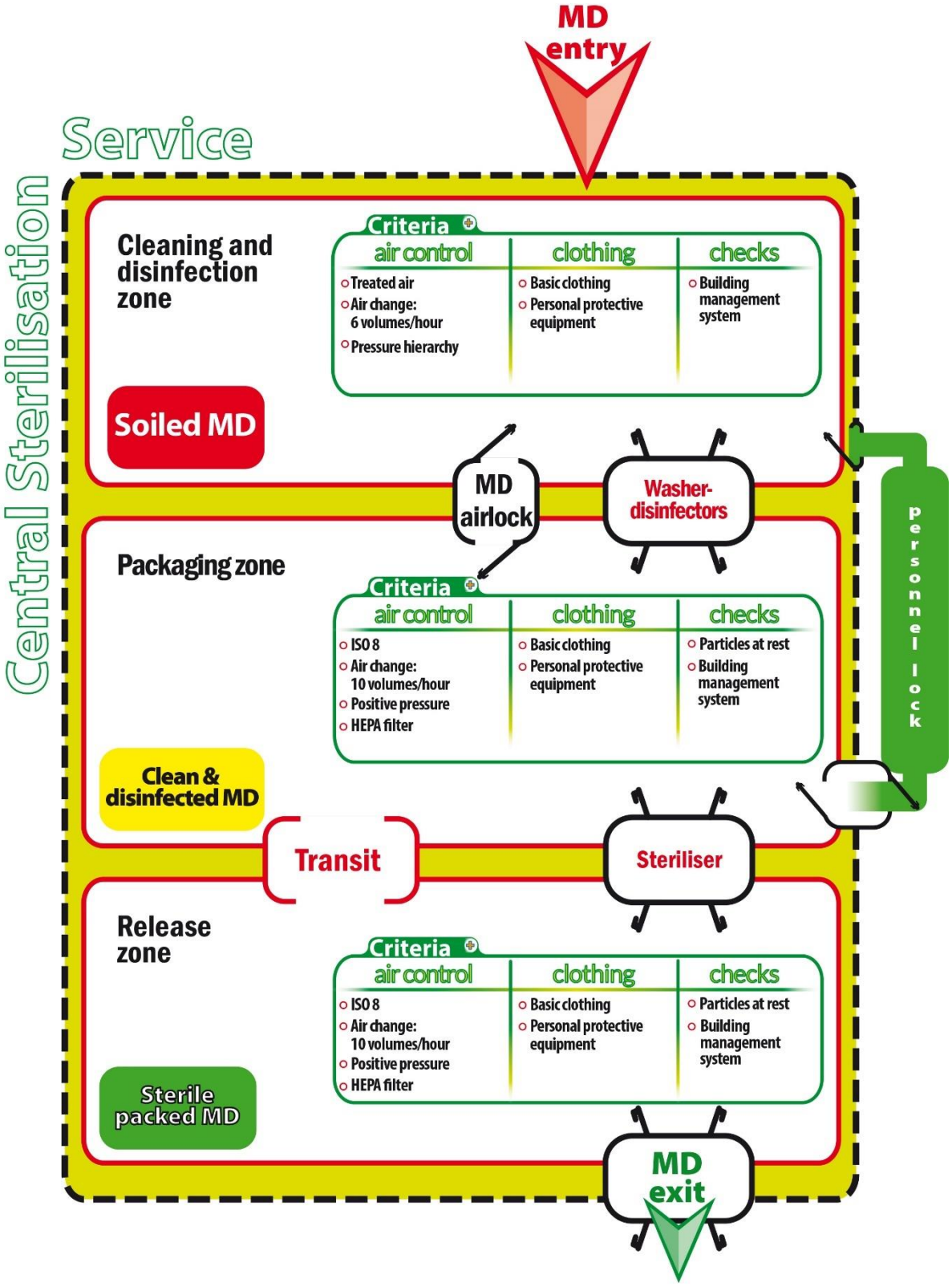
Table 4: Recommended PPE by area within the CSS

CSS area	**Basic clothing**	**Additional protections**		
		Gloves	**Protective apron**	**Protection of ocular, oral and nasal mucous membranes**
Cleaning and disinfection area	Closed suit, disposable cap, closed shoes	Non-sterile nitrile gloves with long cuffs	Waterproof apron	Protection of the work area with a face shield or goggles and/or type IIR surgical mouth mask
Packaging area	Clean, closed suit, disposable cap, closed shoes			
Release area	Clean, closed suit, disposable cap, closed shoes	Heat-resistant gloves for heavy-duty work	Not applicable	Not applicable

Eating, drinking, smoking and bringing personal items such as mobile phones into the MD treatment rooms are expressly prohibited.

[16] e.g. trousers and tunic

Figure 3. Summary of air quality requirements, checks, and clothing in the CSS facility.



6. Ecological aspect

A CSS in a hospital has a significant impact on the environment due to the high consumption of water, energy and materials, among other things. In view of the current climate challenges, it is important to keep this impact on the environment to a minimum and to take into account the interaction with the environment, i.e. to ensure sustainable development, e.g. the circular use of used packaging materials. After removing the adhesive tape from the packaging sheets, these sheets can be transformed into a recycled granulate with which new end products can be made. This already takes place in several CSS/operating room environments in Belgium.

Water and energy consumption can be considered a key element (evaluation criterion) when tendering for new W&D equipment. Efficient water recycling can be applied e.g. by reusing the cooling of steam lines, etc. If water is reused, possible microbiological and chemical contamination must be taken into account. The energy (heat) released by all the processes can be used for other applications.

The correct sorting of (medical) waste is also important to avoid unnecessary incineration. The improper separation of hazardous and non-hazardous medical waste results in the unnecessary use of (expensive) containers and incineration in hazardous waste incinerators. Discarded MDs can be recycled after cleaning and disinfection according to the requirements of the healthcare institution, thus minimising medical waste.

VII PROCESS CONTROL

1. Validation

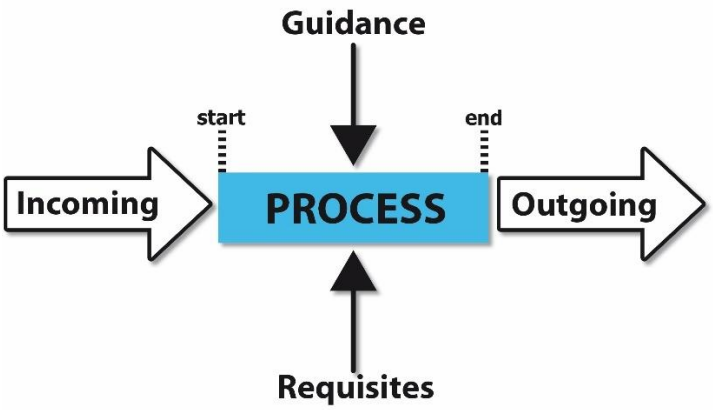
- 1.1. Introduction
- 1.2. Scope
- 1.3. Validation plan
- 1.4. Validation file
  - 1.4.1. Qualification protocols
  - 1.4.2. Test reports
  - 1.4.3. Conclusions on validations
- 1.5. Calibration, adjustment and verification of the measuring chains
- 1.6. Preliminary requirements
  - 1.6.1. Compilation and verification of the equipment's technical data
  - 1.6.2. Water quality in the CSS
- 1.7. Validation of washer-disinfectors
  - 1.7.1. Testing of the main alarms or faults
  - 1.7.2. Cleaning efficiency tests
  - 1.7.3. Thermometric tests
  - 1.7.4. Product dosage tests
  - 1.7.5. Load drying tests
  - 1.7.6. Tests for process residues
  - 1.7.7. Summary
- 1.8. Validation of simple ultrasound baths
  - 1.8.1. Ultrasound action effectiveness test
  - 1.8.2. Summary
- 1.9. Validation of ultrasound WDs
- 1.10. Validation of thermal sealing machines
- 1.11. Validation of sterile barrier systems
- 1.12. Validation of steam sterilisers
  - 1.12.1. Testing of the main alarms
  - 1.12.2. Leak test
  - 1.12.3. Bowie & Dick test
  - 1.12.4. Feed water quality in a dedicated generator
  - 1.12.5. Steam quality
  - 1.12.6. Thermometric tests with an empty chamber
  - 1.12.7. Thermometric tests with load
  - 1.12.8. Test with a PDC
  - 1.12.9. Dryness test
  - 1.12.10. Summary
- 1.13. Validation of vaporized hydrogen peroxide sterilisers (VH_2O_2)
  - 1.13.1. Prerequisites
  - 1.13.2. Calibration of specific critical measurement chains
  - 1.13.3. Determination of the worst case – test with load
  - 1.13.4. Summary
- 1.14. Air quality validation

2. Quality management system
- 2.1. Introduction
- 2.2. Scope
- 2.3. Compliance with standards
- 2.4. Document management
- 2.5. Purchasing and resource management
- 2.6. Personnel and training
- 2.7. Production processes
- 2.8. Infrastructure and process control
- 2.9. Services contracts, customer satisfaction, supplier evaluation
- 2.10. Complaint reporting system and CAPA
- 2.11. Data analysis
- 2.12. Risk assessment
- 2.13. Internal and external audit (evaluation)

3. Tracability system
- 3.1. Introduction
- 3.2. Legislation

In the following paragraphs, the following terms are used:
- client: department that benefits from CSS activity (operating room, care unit, etc.).
- process: activity that transforms input elements into output elements (product). The output elements of one process often form the input elements of the next process.

Figure 4: Process



As the sterility of the end product cannot be checked for each MD, each (sub)process must be validated. The validated processes must then be routinely monitored and the equipment appropriately maintained.

Effective control of the bioburden is essential and can only be achieved by previously validated cleaning and disinfection methods in combination with checks of the environment (premises, ambient air, staff, etc.) in which not only the MD preparation operations are carried out but also the conservation of both finished products and consumables, in particular packaging materials.

1. Validation

1.1. Introduction

Validation is the confirmation, through the provision of **objective evidence**, that the requirements for a specific intended use or application have been fulfilled (ISO 11139, 2018). This objective evidence can be, for example, the results of a test, the performance of calculations or the review of documents.

More specifically, validation mainly involves the verification, recording and interpretation of the results of the tests performed, which guarantee that the process remains within the pre-defined limits and yields a product which meets the requirements (disinfected, sterile, etc.).

Although validation is a more comprehensive process, it is generally described as consisting of three parts:

- Installation Qualification (IQ): the equipment is properly installed.
- Operational Qualification (OQ): the equipment is functioning properly.
- Performance Qualification (PQ): the equipment is functioning properly for the user's specific needs.

For each of these steps, the manufacturer or the firm in charge of the validations must have written a test protocol in accordance with the existing standards and the needs of the end user of the equipment.

The OQ phase cannot start until the IQ phase has been successfully completed. The PQ cannot start until after a successful OQ phase.
The IQ and OQ phases can be carried out by the manufacturer, the installer or even an independent qualified firm in accordance with the manufacturer's operating instructions.
However, the PQ is performed by a different person than the one who performed the IQ and OQ.

These three qualifications must be carried out before the equipment is put into service. Subsequently, to guarantee the proper functioning of the equipment over time and therefore the quality of the finished products, the equipment must not only be maintained in accordance with a maintenance plan previously established by the manufacturer, but must also undergo regular routine testing. The nature and frequency of the latter should be described in a validated, justified procedure, in keeping with current standards. These tests include annual requalification (RQ) and periodic testing such as load release parameters.

Before any validation, the water quality must be checked in accordance with "Water quality in CSS" (VII, point 1.6.2.). The water to be analysed must be taken as close as possible to the point of discharge into the tank.

1.2. Scope

This chapter covers the validation of the following equipment:

- washer-disinfectors,
- simple ultrasound baths,
- ultrasound washer-disinfectors,
- thermal sealers,
- steam sterilisers,
- hydrogen peroxide sterilisers,

and validation of the sterile barrier system and air quality.

1.3. Validation plan

A validation plan must be in place for all automated systems related to the washing, disinfection and sterilisation processes.
The purpose of the validation plan is to define all the tests to be carried out, their frequency and the responsibilities, from the installation of the equipment to the last day of its operation.
It must therefore specify all the tests to be performed during the IQ, OQ, PQ (and routine/RQ test) stages. An example structure for a WD validation plan is shown in Appendix 4.

1.4. Validation file

The validation file generally consists of three parts:

- qualification protocols,
- test reports,
- conclusions.

1.4.1. Qualification protocols

A qualification protocol describes the process to be validated and how the qualification will be performed.
Although there is no specific rule on the subject, a common practice, for the sake of clarity, is to write a protocol for each major step of the IQ, OQ, PQ (and RQ) qualification. All protocols must be approved before tests start.

They must contain at least the following information:

- title (and possibly version number),
- names, dates and signatures of the persons who wrote, checked and approved the protocol,
- date of completion, verification and approval of the protocol,
- objective,
- field of application,
- responsibilities of the different stakeholders,
- reference documents used,
- description of the process: the brief operation of the equipment should be explained. The programmes to be validated and their main characteristics (phases and parameters) must also be detailed,
- description of the tests to be performed: the objective of each test must be presented together with the methodology used and the acceptance criteria. If loads are used, they must be described, as must any packaging and accessories. Any photo that helps to describe the elements of the load is welcome. If probes are used, the choice of the number of probes should be justified.

1.4.2. Test reports

They should contain the following main information:

- the names, dates and signatures of the persons who conducted or participated in the tests,
- the name, date and signature of the person who approved the results,
- the identifiers, calibration dates and expiry dates of the standard devices used for testing,
- the results of each test,
- all the necessary evidence (measurement records, photos, videos, analysis reports, etc.) to justify the results obtained.

1.4.3. Conclusions on validations

The status "compliant" or "non-compliant" must be clearly indicated.

1.5. Calibration, adjustment and verification of the measuring chains

No automated process can operate according to the established specifications if the measurement transmitted to it is incorrect. However, every component of a measurement chain (sensor, transmitter, converter, etc.) has an error and this error is likely to increase with time. It is therefore essential that measurement chains be checked periodically to ensure that their errors do not exceed the limits established to ensure the proper functioning of the process.

The calibration operation involves comparing, under specified conditions, the values indicated by a reference instrument and those indicated by the measurement chain to be calibrated. The calculated error is then used to check (confirm or not) if the instrument is still within the tolerances established for the process. There are three possible scenarios:

1. The measurement chain no longer meets the specifications required by the process and must be adjusted. A new calibration and verification must take place after this adjustment.
2. The measurement chain still meets the specifications required by the process but is close to the maximum allowable limit, so should be adjusted. A new calibration and verification must take place after this adjustment.
3. The measurement chain meets the specifications required by the process, so no action is required.

These operations must be carried out according to the rules. It is imperative that the persons in charge of calibration have sufficient knowledge and experience of metrology, the appropriate reference equipment, a robust calibration method, and the necessary keys and codes to access the calibration menus of the equipment.

These operations are generally performed annually. However, this period may be adjusted if there is objective, factual evidence that the period between interventions needs to be revised. A calibration report and a verification report must be established at the end of these operations.

Any replaced sensor or element of a measurement chain requires the recalibration (and if necessary adjustment) of the measurement chain before the equipment can be put back into service.

1.6. Preliminary requirements

This paragraph lists the main requirements for verifying the performance of the equipment. The standards propose additional tests. It is for the user to decide if additional testing is necessary, depending on the specific characteristics of their equipment, the way it will be used and the expected results, taking into account the level of reliability of the installations.

1.6.1. Compilation and verification of the equipment's technical data

Compiling and verifying technical documentation for new equipment is good practice and is necessary if the equipment is to be correctly used and kept in good condition during its operating period. This data may include:

- electrical diagrams,
- the operating, service and installation manuals,
- certificates,
- technical documents (P&ID[17], supply services, etc.),
- the installed programmes, their parameters and the operating phases,
- the characteristics of the chemicals used, if any (technical and safety data sheets).

[17] P&ID: *Piping & Instrumentation diagram*

1.6.2. Water quality in the CSS

The different types of water quality are listed in the "Water Quality" Chapter (VI, point 3.3). Below is a summary table showing the recommended water qualities for the different stages of the sterilisation process. Many stages are not defined in any standards, so the SHC wanted to propose a **minimum water quality** for these steps to guide users. This proposal aims to maintain the maximum integrity of the MD treated in a CSS as well as the equipment, while guaranteeing the optimal efficiency of the sterilisation process.

Table 5: Summary table of recommended water qualities from the SHC

	Sinks/wash basins	Ultrasound baths	WD[18] pre-washing	WD washing	WD rinsing	WD Disinfection
Standards	/	/	/	/	Drinking water EN 15883	Drinking water EN 15883
Recommended by the SHC	Softened water	Softened water	Softened water	Softened water	Osmosis water EN 285	Osmosis water EN 285

	Steam generator supply	Condensed steam
Standards	Osmosis water EN 285	EN 285 ISO 13060
Recommended by the SHC	Osmosis water EN 285	EN 285 ISO 13060

[18] WD: washer-disinfector

1.7. Validation of washer-disinfectors

This section specifies the requirements and tests specific to the WDs used in the healthcare field for the management of MDs and their accessories.

The critical sensors involved for a WD are the conductivity sensor (if present), the clock and the pilot, recorder and rinse water heating tank temperature sensors. For the values, it is advisable to refer to standard ISO 15883.

1.7.1. Testing of the main alarms or faults

Modern WDs are equipped with factory-validated software, so a double check by the user is necessary. The following example tests can be easily performed:

- door testing: ensure the proper configuration and operation of door management,
- fault indication due to a sensor failure: ensure that the automaton detects a fault on a critical sensor,
- indication of defect due to lack of chemicals,
- fault indication on a failure of the supply services (electrical, water, compressed air),
- cycle locking failure: ensure that an operator cannot remove a load (on the unloading side) at the end of a faulty/non-compliant cycle.

1.7.2. Cleaning efficiency tests

The purpose of this test is to evaluate the effectiveness of the cleaning by detecting the residual contamination (or soiling) of the load at the end of the cleaning phase.

The disinfection phase is deactivated during the cleaning efficiency tests. The drying phase can also be deactivated if this facilitates the detection of residual contamination or soiling.

Three tests with a documented reference load and a stain test will be performed per programme. The test soiling is distributed over the entire load. The manufacturer's recommended drying times must be met before the cycle can be started. At the end of the test, the load is free of any trace of stains and proteins.

1.7.3. Thermometric tests

Thermometric tests should verify that the specified conditions on the inner walls of the chamber, the load carriers and the load are met during the cycle.

The thermometric tests differ because their objectives are different depending on the type of programme chosen and the phase of the programme in progress.

For a **pre-wash phase**, a thermometric test ensures that the temperature is kept low enough to avoid protein coagulation.

For a **wash phase**, a thermometric test ensures that temperatures are properly checked within the expected limits and are maintained within the detergent usage limits.

For a **thermal disinfection phase:**

- a thermometric test of the inner walls of the chamber aims to ensure that the specified minimum temperature is achieved for the specified minimum time, or an equivalent lethality (A_0), is achieved on all walls of the chamber.
- a thermometric test of the load and load carriers must ensure that:
  - the temperature profile defined for the disinfection phase is respected.
  - the specified minimum temperature for the specified minimum time (stationary phase) or equivalent lethality (A_0) is achieved on all surfaces to be disinfected.

For a **chemical disinfection phase:**

- A thermometric test of the chamber walls and load carriers ensures that:
  - the temperature profile defined for the disinfection phase is respected.
  - all temperatures are within the operating temperature range of the disinfectant.
  - all temperatures are within the maximum specified for the types of loads used.

The load tested must be a reference load. The choice of the number of probes-recorders used must be explained in the protocol. Each programme used must be validated. To demonstrate the reproducibility of the results, four consecutive tests must be performed (one "cold" start followed by three "hot" starts).

The applicable criteria are those described in the ISO 15883 family of standards.

1.7.4. Product dosage tests

Measurement accuracy and repeatability tests ensure that the dosing system consistently injects the programmed amount of chemicals. These tests must be performed for each programme used. They should also be an opportunity to verify that the delivered amounts are within the range of concentrations recommended by the chemical manufacturer.

The operator must choose the most suitable method to perform this test, depending on the technical constraints of the equipment.

1.7.5. Load drying tests

The proper drying of washed and disinfected items is important. It prevents corrosion, the growth of microorganisms and biofilm formation. The degree of drying specified by the operator must be achieved.

Checks can take place by the careful and thorough visual inspection of each item in the load and/or by using coloured crepe paper.

1.7.6. Tests for process residues

Although the standard does not mandate the following tests, they may be useful to the CSS manager in resolving cleaning quality issues. The purpose of this test is to evaluate whether the organic matter and chemicals used (detergents, rinse aids, etc.) have been properly removed after the final rinse phase.

Measuring the conductivity of the rinsing water leaving the chamber is an indirect way to ensure that the final rinse is effective and the level of residues is toxicologically harmless. This measurement is compared with the conductivity value of the rinsing water discharged into the chamber.

The limit value not to be exceeded is determined as follows:

conductivity value of the softened water discharged into the chamber
+ limit value of the conductivity related to the detergent[19],
+ limit value of the conductivity related to the drying activator[20].

To ensure reproducibility of results, it is recommended that this test be performed at least three times.

1.7.7. Summary

Table 6: Tests recommended by the SHC as part of the validation of the WD

Tests	IQ	OQ	PQ	RQ
Compilation and verification of the technical data	X			
Verification of the power services	X			
Calibration (and adjustment) of critical measurement chains	X			X(Y)
Door management tests	X			
Tests of the main defect indications	X			
Verification of the quality of the final rinse water		X		X(Y)
Verification of the quality of other water supplies		X		X(Y)
Cleaning efficiency test			X	X(Q)
Thermometric tests of the chamber walls		X		
Thermometric tests - pre-wash and wash phase -		X		X(Q)
Thermometric tests of the load and load carriers - Disinfection phase			X	X(Q)
Chemical dosage tests		X		X(Q)
Drying test			X	X(Q)
Tests for process residues			X	X(Q)

X = Recommended test
X(Q) = Test recommended one to four times per year
X(Y) = Test recommended annually

[19] This limit value must be provided by the detergent manufacturer
[20] This limit value must be provided by the activator manufacturer

1.8. Validation of simple ultrasound baths

There is no specific standard for ultrasound baths, but the following periodic checks can be considered to evaluate the performance of ultrasound equipment.

1.8.1. Ultrasound action effectiveness test

Two simple methods are commonly used for this test: the aluminium foil test and the colorimetric change test.

- Aluminium foil test
  The objective of this test is to highlight the ultrasound waves visually by perforating aluminium strips.

Figure 5: View of the perforation of aluminium strips by ultrasound waves

Criteria:

a. after a cleaning cycle, all aluminium strips must be pierced at the height immersed in the tank.
b. each sheet must have lost ± 20% of the average weight lost by all the aluminium strips.

The test can be performed three times to improve the value of the results.

- Colorimetric change test
  The objective is to ensure that the ultrasound frequency of the bath is between 35 kHz ± 5 kHz by placing, for example, vials with a colorimetric indicator and glass ball in the bath. The number of bottles varies according to the volume of the bath. Other tests can be used.

1.8.2. Summary

Table 7: Tests recommended by the SHC for the validation of simple ultrasound baths

Tests	IQ	OQ	PQ	RQ
Compilation and verification of the technical data	X			
Verification of the power services	X			
Calibration (and adjustment) of critical measurement chains	X			X(Y)
Quality of the water supply		X		X(Y)
Detergent dosage		X		X(Q)
Thermometric tests without load		X		
Ultrasound action effectiveness test		X		X(Q)
Pre-cleaning efficiency test with reference load			X	X(Q)
Thermometric tests with reference load			X	X(Q)

X = Advised test
X(Q) = Test advised one to four times per year
X(Y) = Test advised annually

1.9. Validation of ultrasound WDs

These ultrasound WDs include a disinfection phase and are validated as WDs.
The ultrasound action is validated as for the simple ultrasound baths.

1.10. Validation of thermal sealing machines

The sealing machine must be calibrated and validated annually by the supplier (ISO 11607).

The validation of the sealing machines allows the checking of the compliance of the sealing temperature and pressure characteristics, and even the speed of the sealing band when required. The seal and its imprint on a suitable support allow the validation of their quality, resistance and possible irregularities or defects depending on the type of packaging film used in each CSS (DIN EN 868-5).

1.11. Validation of sterile barrier systems

Part 2 of ISO 11607 specifies the requirements for the development and validation of packaging processes for resterilisable medical devices in the terminal stage. These processes include forming, sealing and assembling preformed sterile barrier systems, sterile barrier systems (SBS) and packaging systems including the microbiological barrier and protective packaging.

Part 2 of ISO 11607 applies to health care institutions, among others.

The validation of SBS aims to demonstrate that they meet the standard by ensuring the creation and conformity of the packaging products through an IQ and an OQ of the products and apparatus used to constitute the SBS. The PQ will demonstrate that the practices ensure the compliance of the final stage of SBS constitution, and the repeatability and reproducibility of the product.

The validation of the SBS will take into account the reality of sterilisation, the production requirements and the diversity of the staff. The test protocol will be carried out under the worst possible production conditions with different people.

As a preamble to the validation and requalification of SBS, it is necessary to:

- document the procedures for the damage assessment, filling and closing of SBSs,
- train operators and assess their skills before starting process qualification,
- determine the worst-case configuration of SBS content.

The frequency of requalification will be defined in the qualification protocol.
A full or partial requalification will be performed for any element constituting a change that affects the condition of the validated package, to train new staff members or to demonstrate that staff still have the knowledge and skills required to perform the processes effectively (ISO/TC16775 B10).

The specific tests for the different SBS will be determined according to the analysis of the risk encountered by the SBS from its forming to its point of use.
Its analysis allows the recording of check points, which must take place regularly to detect unacceptable consequences, as well as potentially dangerous situations, and the taking of the necessary corrective measures.

An SBS used for sterilisation in several different processes will be qualified for each sterilisation process.

1.12. Validation of steam sterilisers

The safety and tightness of the steam steriliser must be checked when the steriliser is purchased and then annually by an external technical inspection service (RD of 18 October 1991).

This section specifies the requirements and tests related to the steam sterilisers used in the healthcare field for the sterilisation of MDs and their accessories.

The **critical sensors** involved for a steam steriliser are the chamber pressure sensors, the clock, and the pilot and recorder temperature sensors (EN 285, ISO 13060).

1.12.1. Testing of the main alarms

- Door tests: locking at the beginning of the cycle, locking of the doors for double door steam sterilisers, locking of the doors at the end of the cycle,
- Indication of fault due to sensor failure (temperature and pressure sensors),
- Indication of fault on a failure of the supply services (electrical, steam, water, compressed air),
- Cycle locking failure: ensure that an operator cannot remove a load (on the unloading side) at the end of a faulty/non-compliant cycle.

1.12.2. Leak test

The purpose of this test is to demonstrate that the rate of air leakage into the steriliser chamber during the vacuum phases does not exceed a level that prevents the penetration of steam into the load to be sterilised and will not potentially risk the recontamination of the sterilised load during drying.

Every steam steriliser is equipped with a leak test programme (or chamber tightness test). At the end of this test, the rate of pressure rise must not have exceeded 1.3 mbar/min.

See also the "Sterilisation process" chapter, X, 1.5.

1.12.3. Bowie & Dick test

See the "Sterilisation process" chapter, X, 1.5.

1.12.4. Feed water quality in a dedicated generator

See "Water quality in the CSS," VI, point 1.6.2.

1.12.5. Steam quality

Beforehand, it is necessary to check the concordance of the parameters in accordance with the Regnault table (table 13).

According to standard EN 285, four tests should be performed on the steam to evaluate its quality:

- non-condensable gases[21]: saturated steam should contain a maximum of 3.5 ml of non-condensable gases from 100 ml of condensate.
- steam content[22]: the content indicates the mass of the gas fraction present in the saturated steam mass. The steam content must be ≥ 0.95.
- overheated steam: When the supplied steam expands at atmospheric pressure, the overheating must not exceed 25 K (25 °C).
- contaminants: condensed steam must be free of contaminants in quantities that may either impair the sterilisation process or contaminate or degrade the steriliser or the sterilised load.

These four tests are recommended during the initial validation; the first three can then be performed at least every five years and as soon as there is a suspicion of deterioration in the steam quality. The quality of the condensate can be checked once a year before requalification.

1.12.6. Thermometric tests with an empty chamber

Thermometric tests with an empty chamber ensure that the temperature within the chamber is homogeneous and that the steriliser respects the parameters of the chosen cycle. They should be performed at least once for each sterilisation programme used.

A sensor layout plan must be prepared and attached to the test report.

The tests highlight the following: balance time, hold time, and temperature during the entire hold time.
The conditions for saturated steam must be met (see Table 13 Regnault table).
No critical alarms should be observed during the test cycles.

Other optional but useful criteria may be specified in the test protocol. For example, the temperature difference between the steriliser probe and the reference probe during the holding phase

1.12.7. Thermometric tests with load

The purpose of thermometric tests with load is not only to ensure that the required temperature is reached at any point on the load during the programmed time, but also that the steam is saturated during the sterilisation phase and that the results are reproducible.

For these tests, it is necessary to define one or more reference loads. A reference load is built up from the range of commonly used and most difficult to sterilise MDs. The packaging system should be identical to that used for routine production.

[21] This method does not necessarily express the true non-condensable gas content of the steam. The limit value was defined experimentally in the 1960s, in relation to the sensitivity of the air detectors commonly used in the UK at that time. Repeated measurements give an accurate picture of the non-condensable gases present in the steam supply.
[22] The test method described in EN 285 should be considered not as a true measurement of steam content, but as a method to demonstrate the acceptability of the steam.

Note: as no single programme is suitable for all loads, it is not uncommon for standard programmes to have to be adapted by the manufacturer (or their local representative) to best suit the specific loads. It is therefore essential that these loads are defined and fully described in the test protocol before validation begins.

Each installed sterilisation programme must be tested. To demonstrate the reproducibility of the process, a minimum of three consecutive compliant tests must be performed per programme.

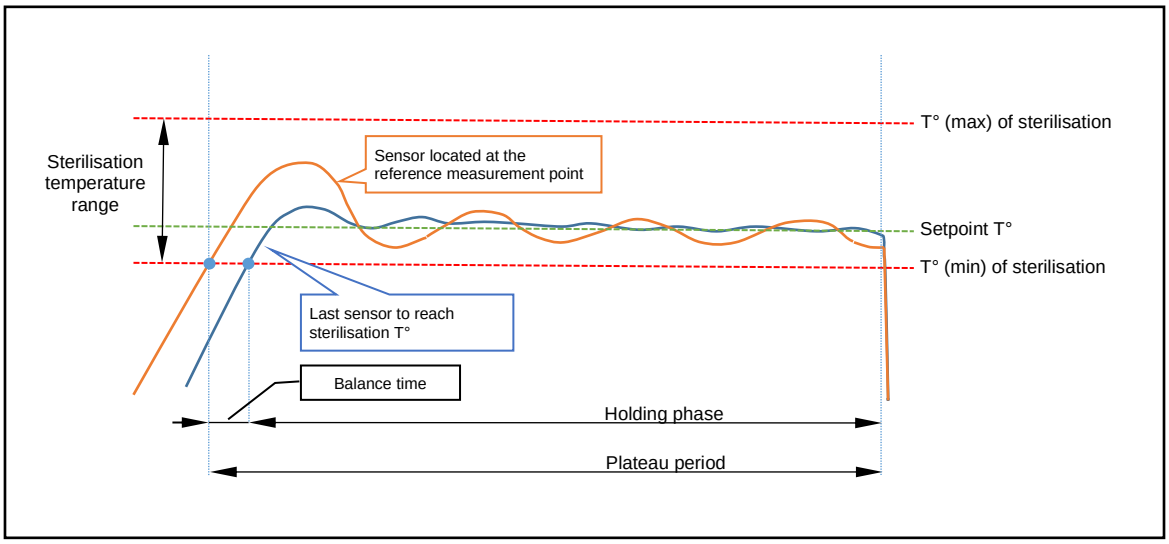
To perform this test, temperature sensors are distributed within the load at the points in the product where sterility is most difficult to achieve. A sensor is positioned near the reference measurement point. An absolute pressure sensor is also positioned at the geometric center of the chamber. Additional sensors can be placed in the chamber if necessary. These sensors must measure and record throughout the cycles to be tested. Several technical solutions can be considered for performing this test (wired system, autonomous recorders, hybrid system). Regardless of the technical solution, it is essential that the measuring system does not influence the sterilisation process.

The number of sensors to be placed in the chamber and the load depends on the volume of the chamber and the complexity of the load. Each component of the load belonging to at least one MD family must be monitored for temperature. For a small steriliser (ISO 16060), the number of sensors should not exceed six. For a large steriliser (EN 285), between 12 and 16 sensors should be sufficient in most cases. The choice of the number of sensors must be justified in the test protocol.

A sensor layout plan must be prepared and attached to the test report.

The tests must highlight the following: balance time, hold time, and temperature during the entire hold time.
The conditions for saturated steam must be met (see Table 13 Regnault table).
No critical alarms should be observed during the test cycles.

Figure 6: Example of the representation of the results of a thermometric test



Other optional but useful criteria may be specified in the test protocol. For example, the temperature difference between the steriliser probe and the reference probe during the holding phase, the pressure difference between the steriliser probe and the standard probe during the holding phase.

1.12.8. Test with a PCD

When a process challenge device (PCD[23]) is used for a hollow load, it must be defined. This device must represent the MD and its packaging.

1.12.9. Dryness test

The dryness test is used to demonstrate that the sterilisation cycle is unlikely to cause moisture problems in the loads.

The principle to be respected is that the sterilised MD must be visually dry. However, the MD may be visually dry and contain residual moisture that could eventually lead to the growth of undesirable microorganisms. For this reason, to evaluate the quality of the drying process more objectively, the standards (EN 285, EN 13060, etc.) recommend weighing the items in the load before and after the sterilisation cycle. Too much post-cycle mass increase indicates an unacceptable amount of residual water.

Criteria:

- absence of residual water on and in the load,
- in the case of a predominantly metallic load: Δ mass of each element ≤ |+0.2%|,
- in the case of a predominantly textile load: Δ mass of each element ≤ |+1%|.

These tests must be carried out at least three times per programme and per type of load.

[23] PCD: *process challenge device*

1.12.10. Summary

Table 8: SHC recommended tests for steam sterilisation validation

Tests	IQ	OQ	PQ	RQ
Compilation and verification of the technical data	X			
Verification of supply/power services	X			
Calibration (and adjustment) of critical measurement chains	X			X(Y)
Door management tests	X			
Tests of the main failure indications	X			
Leak test		X		X(Y)
Bowie & Dick test		X	X	X(Y)
Tests on the quality of the water used to supply the steam generator		X		X(Y)
Steam quality tests (non-condensable gases, content and overheated steam)		X		X(Y)
Condensed steam quality tests (contaminants)		X		X(Y)
Thermometric tests - empty chamber		X		
Thermometric tests - reference load			X	X(Y)
Hollow load test (PCD)			X	X(Y)
Load drying tests			X	X(Y)

X = Advised test
X(Y) = Test advised annually

1.13. Validation of vaporised hydrogen peroxide sterilisers (VH_2O_2)

This section specifies the requirements and tests related to the sterilisers using H_2O_2 in a gaseous state (VH_2O_2) as a sterilising agent and used in the healthcare field for the sterilisation of MDs and their accessories.

1.13.1. Prerequisites

For the parametric qualification of VH_2O_2 sterilisers, the ISO 22441 (2022) standard has recently been made available. Currently, both ISO 22441 and 14937 are applicable for VH_2O_2 process validation.

1.13.2. Calibration of specific critical measurement chains

The relevant **sensors present** for the process variables in a H_2O_2 steriliser are the chamber pressure sensors, the clock, the temperature sensors and the H_2O_2 concentration sensor (if any).
The calibration of other sensors may be necessary depending on the design of the steriliser.

1.13.3. Determination of the worst case - Test with load

A reference load must be defined for these tests. It can be:

- either a PCD with a biological indicator considered by the manufacturer or the firm in charge of the validation as being representative of what is the most difficult to sterilise, distributed in the chamber.
- or a specific load defined by the user and considered by them to be representative of what is most difficult to sterilise in the context of their use. However, special care must be taken when defining the load because in H_2O_2 sterilisation, unlike saturated steam sterilisation, the volume and mass of the load components are not relevant. What is important here is the surface to be sterilised with an inoculum or biological indicator at the most difficult to reach place. Cavities and lights can therefore be problematic. Some materials, such as silicone, can also make sterilisation more complex by absorbing H_2O_2.

Each installed sterilisation programme must be tested to demonstrate the reproducibility of the process. The validation strategy chosen for VH_2O_2 suggests applying the tests to the half-cycle of the processes present.

1.13.4. Summary

Table 9: SHC recommended tests for H_2O_2 sterilisation validation

Tests	IQ	OQ	PQ	RQ
Compilation and verification of the technical data	X			
Verification of the power/supply services	X			
Calibration (and adjustment) of critical measurement chains	X			X(Y)
Door management tests	X			
Tests of the main failure indications	X			
Tests without load		X		
Tests with load			X	X(Y)

X = Advised test
X(Y) = Test advised annually

1.14. Air quality validation

As mentioned in the "air control" section (VI, point 3.2.), ISO level 8 (according to ISO 14644) is required for the packaging and release area. It involves a particle count.
Only particle count tests are required by the standard as they provide a guarantee of results. The other tests are optional and should be considered if the particle count test fails.
This particle count test requires a minimum number of sampling points deduced using the following equation: $N_L = \sqrt{A}$

where N_L is the minimum number of sampling points
A is the section of the area to be checked (m^2).

The sampling points must be evenly distributed throughout the packaging area and located at the height of the activity according to a pre-established protocol.
The volume taken at each point must be at least two litres and the sampling time must be at least one minute.

Table 10: Maximum allowable concentrations (particles/m^3 of air) of particles equal to or greater than the size given below

	0.1 µm	**0.2 µm**	**0.3 µm**	**0.5 µm**	**1 µm**	**5 µm**
ISO 8				3,520,000	832,000	29,300

Table 11: SHC recommended tests for air quality validation

Tests	RQ
Airborne particle counting	X(Y)
Ultrafine airborne particle counting	O
Airborne macroparticle counting	O
Air flow measurement	O(Y)
Reading of the pressure cascade	X (Y)
Search for leaks on an installed filtration element	O(Y)
Test of the airflow direction and its visualisation	O(Y)
Temperature reading	X (Y)
Moisture reading	X (Y)
Electrostatic test and ion generator test	O
Particle sedimentation test	O
Containment leak test	O(Y)
X(Y) = Test recommended (annually) O(Y) = Optional test (annually)	

2. Quality management system

2.1. Introduction

It is the responsibility of each CSS to ensure the quality of the final sterile product. As part of his duties, the hospital pharmacist is ultimately responsible for guaranteeing this quality and setting the criteria for it. The CSS head nurse is responsible for the implementation, checking and monitoring of procedures and processes based on mandated criteria and indicators. The procedures are validated by the relevant committees (such as the Hospital Hygiene Committee (HHC) and the Medical Equipment Committee (MEC)).
In this particular chapter, when reference is made to the responsibility of the CSS, it refers to the hospital pharmacist in charge and the CSS head nurse.

A CSS must use a quality management system to guarantee this quality. It may be a quality system that is part of the hospital-wide quality policy and quality assurance process. However, the specific nature of the sterilisation process requires a Quality Management System (QMS) developed for the CSS. Through this QMS, the hospital pharmacist, in collaboration with the management committee, will ensure that current regulations are met in the daily CSS process and that there is a continuous improvement process based on audits and data analysis, as well as a reporting system. One of the foundations of this data capture and process monitoring is the traceability system. This point is dealt with separately in Chapter VII, point 3.

This QMS must include at least the following:

- an elaborate scope of application,
- compliance with standards,
- document management,
- purchasing and resource management,
- personnel and training,
- production processes,
- check of the infrastructure and process,
- service contracts, customer satisfaction, supplier evaluation,
- a complaint reporting system and CAPA[24],
- data analysis,
- risk assessment,
- an internal or external audit (evaluation).

The certification of a central sterilisation service according to ISO 13485 is recommended. This MD quality system best meets the process check needs of the CSS.

Below is an overview of the above-mentioned elements that can be used as a basis for a QMS.

[24] CAPA: *corrective action and preventive action*

2.2. Scope

A fundamental part of implementing a quality system is determining the scope of the CSS in the quality manual. It clarifies what the CSS will commit to in the organisation and around what it will develop its quality system. To measure the objectives in this area, the CSS will establish a number of Key Performance Indicators (KPIs).

This scope must be part of a hospital-wide quality policy, visibly supported by hospital management, and part of its action plan. There must be a document in which one or more members of management approve the quality policy within the CSS.

2.3. Compliance with standards

The CSS should develop documentation that clearly indicates the standards on which its processes are based and how they are met. These standards cover quality, equipment, consumables, staff, process check, environment, etc.

2.4. Document management

A large number of documents are developed within a CSS to describe the CSS process, such as general procedures or specific work instructions. The CSS must implement a system to demonstrate its control of document management. Managers must ensure that the documents used are up to date, available and accessible to everyone and that no outdated documents are on site.

This document management applies to all paper and digital documents used within the CSS. Preference is given to document management systems with digital support.

2.5. Purchasing and resource management

The CSS must have demonstrable control over the purchase of the materials it uses. These materials must comply with the laws and regulations in force. In collaboration with the purchasing service, the CSS establishes a procedure for the purchase of any material or equipment that has a direct effect on the quality of the final sterile product.

2.6. Personnel and training

A CSS must ensure that all operations are performed by trained and qualified staff with certification recognised by official agencies. To this end, a basic profile (job description) is drawn up for recruitment by the hospital's Human Resources (HR) service.

An ongoing skills assessment is conducted in accordance with institutional policy. This evaluation must be documented.

The CSS also provides a continuous training plan for all staff members to maintain the level of skills acquired. This level of qualification of each staff member must be available and visible.

2.7. Production processes

The CSS is a production service that must ensure the delivery of a high quality sterile end product. Within the quality system, documents must be available that describe and clarify these different processes. A distinction is made between general work procedures and specific work instructions.
Procedures must be visibly implemented on the ground and known to CSS staff.

2.8. Infrastructure and process control

To guarantee the quality of the processes, the CSS establishes procedures describing how the checks are performed and recorded. These checks apply to infrastructure, equipment, and process quality.

2.9. Service contracts, customer satisfaction, supplier evaluation

The CSS develops a policy for end-user contact. The CSS documents the rights and obligations of each party through SLAs (Service Level Agreements), with patient safety as a priority. The CSS can enter into these SLAs with a large group or with individual customers. The SLA describes mutually determined KPIs, which are evaluated in an annual satisfaction survey and sent to customers and management. Action plans are developed to improve the processes, if necessary.

It is also advisable to enter into SLAs with hospital support services that provide services to the CSS (e.g. technical service, maintenance service, etc.)

2.10. Complaint reporting system and CAPA[25]

The CSS uses a system, preferably digital, where customers can report problems at any time. A procedure defines how and when notifications will be processed.

In the event of repeated or serious non-conformities, an analysis of the causes and their impact is mandatory as are corrective and preventive actions to improve the process.

2.11. Data analysis

To determine the adequacy, effectiveness and compliance of the QMS, the CSS must collect data through the traceability system, process control records, audits, satisfaction survey results and service reports. The analysis of this data will determine whether the objectives set (KPIs, quality indicators) have been achieved.

The CSS will use these analyses for annual feedback to management. Through this, the CSS will demonstrate to management and customers that the QMS is effective and will set new strategic goals.

[25] CAPA: *corrective action and preventive action*

2.12. Risk assessment

In addition to identifying the causes and effects of the potential failure of a process or a means of production, the objectives of a risk analysis are to identify the actions that can eliminate this potential failure (or at least reduce its impact and/or frequency).

This involves identifying the dysfunctions that lead to failure before they occur. It is therefore essentially a predictive method. These risk analyses are documented and repeated periodically.

For the sterilisation process, a risk analysis can be performed initially on the general CSS requirements, with a focus on basic needs (water, electricity, network, etc.), facilities and equipment. These elements have an immediate impact on the production process. In a second step, the focus can be on specific CSS processes that have a possible impact on the qualitative sterile end product (e.g. the impact on the sterile end product of an undetected WD failure).

One method of evaluating potential failures can be the FMECA method (**F**ailure **M**ode, **E**ffects and **C**riticality **A**nalysis) (Appendix 5).

2.13. Internal or external audit (evaluation)

The CSS will periodically verify the accuracy, effectiveness and performance of the established procedures and work instructions through internal and external audits. The elements to be audited will be determined on the basis of risk analyses carried out in advance, in which the most critical elements have been determined. The following items will always be part of the audits:

- all critical processes that have a direct effect on the final sterile product,
- all critical external and internal suppliers (e.g. establishing supplier evaluations for packaging materials, equipment, HR, technical service, etc.),
- the traceability system.

The service establishes audit lists containing the most important quality and process elements to be checked. The effectiveness of certain control mechanisms will also be tested during these audits. The results are documented and analysed. Where applicable, the necessary action plans are drawn up to eliminate the defects found.

These audits must be performed by trained and preferably certified persons. At least one audit per year should be conducted by someone from outside the organisation.

3. Traceability system

3.1. Introduction

Traceability in a CSS contributes to the good management of the MD and to the legal protection of the institution. Traceability is understood as the implementation of a system for tracking the MD at all stages of its life cycle and the proactive introduction of the desired processes. It is an essential part of a quality system. It is recommended that each healthcare institution implement such a system by referring to the ISO 13485 standard. The traceability of MDs is computerised.

This traceability has several objectives:

- safe: it guarantees patient safety by tracing each step of the sterile manufacturing process from use to reuse, based on an identification code for the set or the MD.
- economic: it allows an estimation of the productivity of the service, the costs generated, the staffing needs, the volume of the MD stores and their condition, etc.
- organisational: the system allocates the available resources according to production needs. It also ensures the standardisation of MD management processes.

Every set/MD must have a label with an identification code that allows its use in a patient to be traced and linked to the sterilisation process and the history of the set/MD.

Traceability to the MD should be considered. This unique MD identification code can currently be done by datamatrix or RFID (Radio Frequency Identification).

Other information may be present on the label as part of the operation of the services. This information is described in Chapter IX: "composition and packaging".

A data backup of 16 years should be considered[26]. The identification code must be mentioned in the patient record and in the traceability software, while complying with GDPR rules[27].

MDs that enter the hospital must be identified in the traceability system. Suppliers providing a set must also provide a set identification code for the set that meets the same requirements as those for hospital-owned sets (composition, usage history, etc.).

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[26] In accordance with **MDR 2017/745**, Annex XI, Part B. Administrative Provisions
The manufacturer or its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:
- the EU declaration of conformity,
- the documentation referred to in Section 12 of this Annex,
- the certificate referred to in Section 15.2. of this Annex, and
- the EU-type examination certificate referred to in Annex X.

Section 8 of Annex IX shall apply.

In accordance with **Art. 25 of the Law on hospitals of 23 October 1964 and Art. 6 of the RD 15/12/1978**, the patient's medical record must be kept for 30 years.

[27] GDPR: General Data Protection Regulation

3.2. Legislation

According to the requirements of EU Regulation 2017/745, manufacturers must identify MDs with a Unique Device Identifier (UDI).

The regulations classify reusable surgical instruments according to their risk:

- class I when they have a temporary use (less than 60 minutes) (point 5.2 - rule 6 + Annex VIII, Chapter 1, Point 1 of MDR 2017/745)
- classes IIa, IIb and III according to certain specificities.

Class I devices do not have to be identified.
The manufacturer and the MD notifying body determine the class of the MD (this information is contained in the technical file). The declaration of conformity of the MD marketed under the MDR must indicate the risk class of the MD.

In Belgium, the Royal Decree of 27 September 2020 defines a list of class III devices that must be traced when used on a patient.
APPENDIX - List of medical devices referred to in Chapter 1 of this decree.

- *Stent;*
- *Neurostimulator;*
- *Cochlear implant;*
- *Hydrocephalic shunt;*
- *Orthopaedic implant;*
- *Implant for aesthetic or reconstructive purposes within the scope of Medical Devices Directive 93/42/EEC or the regulation;*
- *Electrode and biosensor;*
- *Mechanical heart implant;*
- *Electronic and electrical heart implant;*
- *Ophthalmic implant.*

For non-class III implantable MDs, Member States must encourage and may require healthcare facilities to record and retain the UDI supplied to them.

The national legislation provides for the possibility of an extension to other classes of MD.

The MD Law of 15 December 2013 provides in Article 51 that:

§ 13. The King may, with a view to protecting public health, by a decree deliberated in the Council of Ministers, and after obtaining the opinion of the commission created or designated by him in application of Article 9, § 4, of the Law of 25 March 1964 on medicinal products, extend the application of this article to medical devices other than implantable medical devices, on the basis of the risk that these may represent for public health and patients.

VIII CLEANING AND DISINFECTION

1.Introduction

2.Management of soiled/used MDs

3.Cleaning and disinfection methods
- 3.1. Pretreatment
  - 3.1.1. Cold pre-rinsing
  - 3.1.2. Pre-soaking
  - 3.1.3. Ultrasound pretreatment
  - 3.1.4. Manual pretreatment
- 3.2. Machine cleaning and disinfection
  - 3.2.1. Thermal disinfection
  - 3.2.2. Chemical disinfection
- 3.3. Manual cleaning and disinfection
- 3.4. Permanent checks
- 3.5. Validation

1. Introduction

The cleaning and disinfection of reusable MDs are not only essential steps prior to the sterilisation process, but also contribute to the safe handling of the MDs by the staff in the subsequent areas.

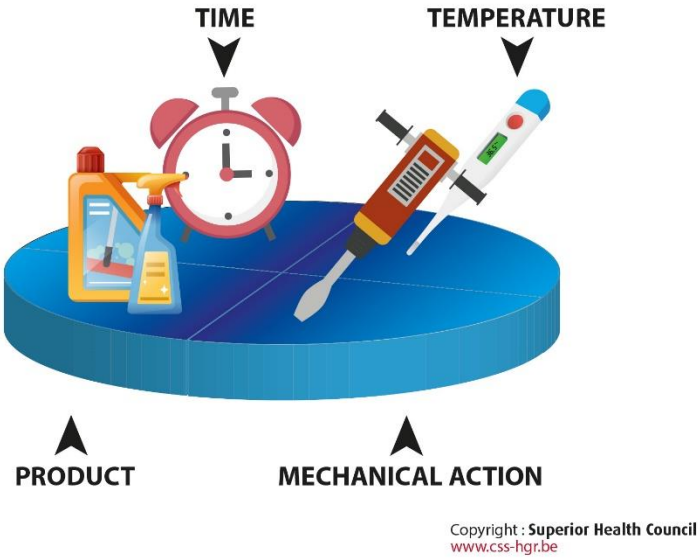
A proposed MD is always considered and treated as potentially contaminated. Given the nature of the potential contamination and the sometimes high degree of soiling, it is necessary to limit preliminary handling, especially manual handling, as much as possible. Properly maintained equipment in the washing and disinfection area, validated processes (ISO 15883), detergents that comply with EC Class IIb according to the European Medical Device Regulation (MDR 2017/745) and the use of the appropriate devices ensure a good cleaning and disinfection process. All washing equipment, such as cloths, brushes, etc., is for **single use** only.

Machine cleaning and disinfection are considered the standard methods because they are reproducible, verifiable and documented. Manual cleaning and disinfection are reserved for exceptional cases and must be carried out in accordance with the manufacturer's instructions.

In addition to water, the basic principle of good cleaning is the "Sinner Circle", which describes/defines the synergy of four parameters for optimal cleaning:

- temperature: the impact of temperature on different elements during the process (detergent, MD, types of soiling, etc.),
- duration: impact of the duration of the different steps of the process,
- product: type of detergent, concentration,
- mechanical activity: active dirt removal method (hydraulic force, brush, etc.).

Figure 7: Sinner Circle



Each of these parameters has an impact on the end result of the cleaning and they are interrelated. If one of these parameters is changed or adjusted, the impact must be assessed and, if necessary, one or more of the other parameters must be changed to ensure the qualitative end result.

2. Management of soiled/used MDs

The user ensures that after use, the set with the MDs is transported in full, tidy and free of sharps, debris, single-use MDs, etc.
Corrosive substances should be removed as soon as possible.
The used MD is transported to the CSS in a dry condition, as quickly as possible, and in a closed container (cart, bin, etc.). For external transport where the MDs used are on public roads, this must be indicated by a pictogram on the materials or carts concerned, as required by the ADR[28].

Cleaning and disinfection are carried out in the CSS.

[28] ADR : *Agreement for Dangerous goods by Road* which applies in Europe. https://unece.org/fileadmin/DAM/trans/danger/publi/adr/adr2017/ADR2017F_web.pdf)

3. Cleaning and disinfection methods

3.1. Pretreatment

To ensure better cleaning and disinfection efficiency, the MDs are opened and disassembled, if necessary, and placed in the set. The set is duplicated if necessary.

Additional pre-treatment is required, depending on the type of MD, the contamination present or the manufacturer's specific instructions in the Instructions for Use (IFU[29]). This pretreatment may consist of or be a combination of the following:

- cold pre-rinsing in a sink or pre-rinsing using an automatic unit
- pre-soaking in a sink with a suitable product or detergent,
- ultrasound treatment,
- manual pre-treatment with brushes, water and air guns, and steam equipment.

3.1.1. Cold pre-rinsing

Depending on the type of surgery, there is a difference in the degree of soiling of the MDs offered in the CSS. Heavily soiled sets are preferably rinsed and flushed before cleaning and disinfection.
This can be done with an automatic pre-rinse device or a strong jet of water from a sink shower.

3.1.2. Pre-soaking

It may be necessary to pre-soak the affected MDs to treat encrusted or dried dirt. This operation involves:

- immersing the affected materials in a sink with a suitable detergent (enzymatic or alkaline) **or**
- putting the part of the MD to be treated directly in contact with a specific active product (for example hydrogen peroxide).

3.1.3. Ultrasound pretreatment

The ultrasound device is a useful tool for removing soiling from areas that are difficult to access with sprinklers and/or brushes. Ultrasound treatments are also recommended for mechanically fragile MDs (microsurgery, MDs for dental use). The MDs must be compatible with the ultrasound treatment (according to the manufacturer's instructions). When using ultrasound, the following should be considered:

- use an appropriate cleaning and/or disinfecting agent,
- adjust the water temperature according to the products used,
- change the water in a timely manner in accordance with established procedures,
- test the equipment for correct operation at least once a week with a commercially available PCD.

[29] IFU: *instructions for use*

3.1.4. Manual pretreatment

Manual pre-treatment can be used to guarantee the quality of the subsequent cleaning process or on the basis of the IFU. This includes all the manual cleaning actions performed prior to machine cleaning and disinfection:

- swabbing of lights or other hard-to-reach areas. While there is no guarantee that the affected area will be reached during machine cleaning, this action should guarantee a 100% cleaning result.
- Removal of soiling by spraying with water and air.

3.2. Machine cleaning and disinfection

In accordance with the international standard (ISO 15883) and national guidelines, only validated machine cleaning and disinfection processes may be used. The general requirements for cleaning and disinfection devices are described in Part 1 of ISO 15883. These mechanical processes include a thermal and/or chemical disinfection phase. The IFU of the WD and MD manufacturer should be followed to ensure correct use.

To achieve a correct cleaning result, the washer-disinfector (WD) must be loaded in such a way that each MD is optimally subjected to all the process parameters. This can be achieved by specially designed washing programmes, the necessary connections or special loading carts and by avoiding spray shadows.

Transport carts and containers are best cleaned and disinfected in a cart-washer. If the MDs are also treated in the cart-washer, the necessary validation and periodic testing are required.

For the cleaning process combined with **chemical and/or thermal disinfection**, the following detergents are recommended:

- alkaline detergent,
- enzymatic detergent.

Some optional products can be added after cleaning:

- neutralising agent when using highly alkaline detergents,
- drying agent (caution: degradation of the integrity of certain plastics, e.g. ophthalmological material).

Machine wash and disinfection cycle

A complete wash cycle includes at least the following phases:

- pre-rinsing: removal of coarse dirt and/or residues from the pretreatment process,
- washing: effective cleaning of the MD with detergents,
- rinsing: removal of residues from the cleaning cycle,
- disinfection: high-level disinfection is achieved by thermal or chemical means,
- drying.

Note: to avoid the adverse effects of TASS (Toxic Anterior Segment Syndrome) due to chemical contamination, additional rinsing is recommended for certain MDs used in ocular surgery.

3.2.1. Thermal disinfection

Thermal disinfection is performed with reverse osmosis (RO) water.

Since the F_0 concept is used to determine the sterilising value (appendix 6), ISO 15883 has incorporated the A_0 concept for thermal disinfection.
"A" is defined as the equivalent duration in seconds at 80°C for achieving a given disinfection effect. When the stipulated temperature is 80°C and the Z value is 10°C, the term "A_0" is used.

$$A_o = 10^{\frac{(T-80)}{Z}} * \Delta t$$

Z = 10°C (thermal destruction factor)
T = observed temperature
Δt = time interval (seconds)

Table 12 lists a number of temperatures and the corresponding times that can be used to achieve reliable thermal disinfection.

Table 12: Guide values for temperature and contact time for thermal disinfection.

Temperature in °C	A_0 = 600		A_0 = 3,000	
	Time in seconds	Time in minutes	Time in seconds	Time in minutes
80	600	10	3,000	50
90	60	1	300	5
93	30	0.50	150	2.5

To disinfect MDs that will subsequently be sterilised, an A_0 value of at least 600 must be reached.
An A_0 value of at least 3,000 must be reached to disinfect an MD that will not be sterilised (ISO 15883-2) (= high-level disinfection).

3.2.2. Chemical disinfection

Chemical disinfection is reserved for the machine treatment of heat-sensitive MDs (e.g. Doppler probe or flexible ureteroscope).

The (chemical) disinfection phase is carried out by mixing demineralised or osmosed water and a disinfectant validated for machine use. This product must guarantee a high level of disinfection. When making a choice, the following information must be taken into account:

- the chemical disinfectant must comply with European standards (CE marking and classified according to MDR 2017/745).
- the product used must be compatible with the MD according to the manufacturer's recommendations.

The final rinse uses osmosed water at a maximum temperature of 60°C.

3.3. Manual cleaning and disinfection

As manual cleaning and disinfection are neither reproducible, verifiable nor documented, they are reserved for **exceptional** cases and only for MDs that cannot be cleaned in a machine and in accordance with the manufacturer's recommendations. The manufacturer must provide a validated cleaning and disinfection procedure and the validation protocol that will allow the CSS manager to validate this procedure.

Manual cleaning is always followed by manual chemical disinfection. The MD is then rinsed if the recommendations of the disinfectant manufacturer stipulate this. The disinfectant manufacturer's recommendations regarding the need to rinse the MD should be followed.
Drying is most effective in a drying cabinet. The alternatives are medical compressed air or lint-free disposable towels.

3.4. Permanent checks

The permanent checks are carried out before the MD is packaged.
The following parameters are monitored:

- the cycle parameters: temperature and time (A_0),
- the dryness of the load.

If any of these checks are not in compliance, the appropriate action should be taken before packaging.

3.5. Validation

A validation plan must be in place for all automated washing and disinfection processes (see "Validation" Chapter VII, point 1).

IX COMPOSITION AND PACKAGING

1.Checking and maintenance of MDs

2.Replacement of MDs

3.Requirements for instrument support baskets
- 3.1. Material
- 3.2. Dimensions and weight
- 3.3. Layout
- 3.4. Fasteners
- 3.5. Identification of the MD in the tray

4.Composition of the sets

5.Contaminants

6.Packaging and wrapping
- 6.1. General observations
  - 6.1.1. Standards
  - 6.1.2. Application
- 6.2. Packaging materials and methods
  - 6.2.1. General observations
  - 6.2.2. Packaging with sheets
  - 6.2.3. Packaging using pouches
  - 6.2.4. Containers
  - 6.2.5. Textile

7.Labelling

1. Checking and maintenance of MDs

Each instrument, MD and tray is checked and maintained according to the manufacturer's instructions (IFU) before packaging and sterilisation.

1. MDs must be visually clean.

If there is any doubt about the cleanliness of the MDs, they must be washed and disinfected again.
Several devices can be used during the inspection, e.g. lamp equipped with a magnifying lens, magnifying camera, microscope, flexible endoscope.

2. MDs must be maintained.

To preserve proper functioning, the MDs must be maintained after each cleaning and disinfection, before the functional check. After cooling and in accordance with the manufacturer's recommendations, moving parts and motors will be lubricated, with additional care taken with lenses, cameras, lighting cables, etc.
Excess maintenance product can be removed with a lint-free cloth.

Maintenance products for MDs must:

- be biocompatible,
- be suitable for sterilisation by the chosen sterilisation method, and
- be permeable to the sterilising agent (ISO 17664).

Note: MDs cannot be treated with cleaning agents containing silicone oil. This could make it more difficult to operate the MDs and affect the effectiveness of steam sterilisation.

3. The integrity of the MDs is verified.

The integrity must be verified according to the IFU or AKI[30].
This includes:

- the absence of corrosion, scratches, cracks,
- the absence of damage, wear and tear and deterioration,
- the integrity of the MD sheathing,
- etc.

4. The functionality of the MDs must be verified

The functionality must be verified according to the IFU or AKI.
All MDs that can be taken apart must be reassembled during the functional check.
The check includes, in particular:

- the cutting mechanism of scissors, punches, etc.,
- the ability to grip and hold of needle holders, pliers, clamps, etc.,
- the functionality and integrity of optical cables, electrical cables and light guides,
- the efficiency of fittings, valves and taps,
- the correct operation of the motor.

In accordance with the IFU, it may be necessary to disassemble MDs after inspection and before sterilisation.

2. Replacement of MDs

All non-compliant instruments must be repaired or replaced. Non-repairable MDs are discarded.
New or repaired MDs undergo at least one complete cleaning and disinfection cycle before use.

[30] AKI: *Arbeitskreis Instrumentenaufbereitung*

3. Requirements for instrument support baskets

The MDs are placed in trays/baskets to be cleaned, disinfected, sterilised, transported and stored safely until they are used.
Two types of support are used, depending on the type of packaging used for sterilisation:

- for sheets or laminates: flat bottom and perforated or fine-mesh walls*.
- for containers: wall and basket with a raised wire flat bottom

*To avoid the perforation of the SBS, the tray should not have protruding or sharp edges or supports.

If stainless steel baskets are intended by their manufacturer to store MDs during their cleaning and sterilisation, then they are considered as products specifically intended for cleaning, disinfection or sterilisation either as accessories to MDs or as devices referred to in Article 1, paragraph 4, and those referred to in subparagraph 1 of this point of Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/CEE. These baskets are therefore deemed to be MDs and follow the same level of requirements (CE marking, etc.).

3.1. Material

The recommended material is stainless steel. Synthetic materials are "not recommended" due to the chemical and physical impact of the processes (degradation and fragility of synthetic materials). This makes the drying process more difficult.
The tray must be replaced in the event of damage or loss of integrity.

3.2. Dimensions and weight

The surface of the baskets must have the dimensions of DIN[31], ISO or one of its derivatives.
The maximum weight for an MD set is 10 kg in accordance with standard 868-8, 8.5 kg in accordance with ISO 11228-1 and NBN-EN 1005-1. For ergonomic reasons, the **SHC** recommends that the basket with its contents not exceed the **maximum weight of 8.5 kg** (DSMH, 2010).

3.3. Layout

An MD tray contains only one layer of MDs. It must be possible to move an optional second layer in a single movement.
The shape and arrangement of the supports must not hinder cleaning and disinfection (shaded areas, overloading, etc.). The same applies to the sterilisation process.
The layout of the MD is determined in consultation with the user according to the care procedure.

[31] Deutsches Institut für Normung

3.4. Fasteners

The MDs can be fastened according to the needs: overview of the set/tray, delicate MD, sharp MD, for transport, etc.
MD fastenings must be designed so that cleaning, disinfection and sterilisation are not compromised. In other words, there is minimal contact between the MD and the fastening material.
Examples of possible fastenings:

- fixing points and supports,
- radial fastening or comparable system,
- by means of separation with metal strips,
- fixing mat.

3.5. Identification of the MD in the tray

The MD can be identified (location, reference, etc.) on the tray by means of a printed or engraved marking on a suitable sterilisation-resistant support.
Contaminants (adhesive tape) are not permitted.

4. Composition of the sets

The recomposition of the sets will take into account several rules:

- placement of MDs according to the operating times,
- placement of MDs according to user requirements,
- MDs of the same family are placed together;
- heavy MDs are placed below lighter or more fragile ones;
- fragile and sharp MDs are protected;
- MDs must be fully accessible to the sterilising agent, for example, in the lights;
- the MDs are reassembled; hinged MDs are closed to the first notch if they are accessible to the sterilisation agent or according to the IFU;
- different types of equipment should be limited in the same set.

Particular attention must be paid to titanium MDs and implantable MDs due to their corrosion by galvanisation in contact with stainless steel material; they must be isolated from other MDs in the tray.

Hollow containers (basins, bowls) placed on the MDs prevent proper sterilisation and drying. They are strongly discouraged in the set for the homogeneity of the cycle.

Only the MDs necessary for a single procedure or treatment can be put in the same packaging (one set = one treatment).

5. Contaminants

Pre-printed content lists, instructions, photographs, etc. should not be placed in a set with MDs. For set identification, only labels and tags may be allowed **on the support** (but **not** on the MDs) and must be intact. The MD will be identified by datamatrix or other (see Chapter "Traceability System", VII, point 3).
Adhesive tapes on MDs (colour) compromise sterility and patient safety as they have associated risks of peeling, dirt accumulation and adhesive residue. They are therefore **prohibited**. The use of these tapes also causes the corrosion of the MD near the tape.

6. Packaging and wrapping

The cleaned and disinfected MD must be packaged in such a way as to ensure sterility until the time of use and allow aseptic presentation.

The packaging is validated from the time the package is made until it is used (see Chapter VII, point 1.11).

The choice of materials and packaging always depends on the sterilisation method to be used, the nature of the MDs to be sterilised and the conditions in which they are transported, stored and used.

6.1. General observations

6.1.1. Standards

The packaging system must comply with ISO 11607- 1 and -2 and EN 868-1 to 8.

ISO 11607-1 specifies the requirements for the materials and packaging systems, including the qualification of the packaging system design and the evaluation of their design. The second part of the standard (ISO 11607-2) deals with the validation of packaging processes.

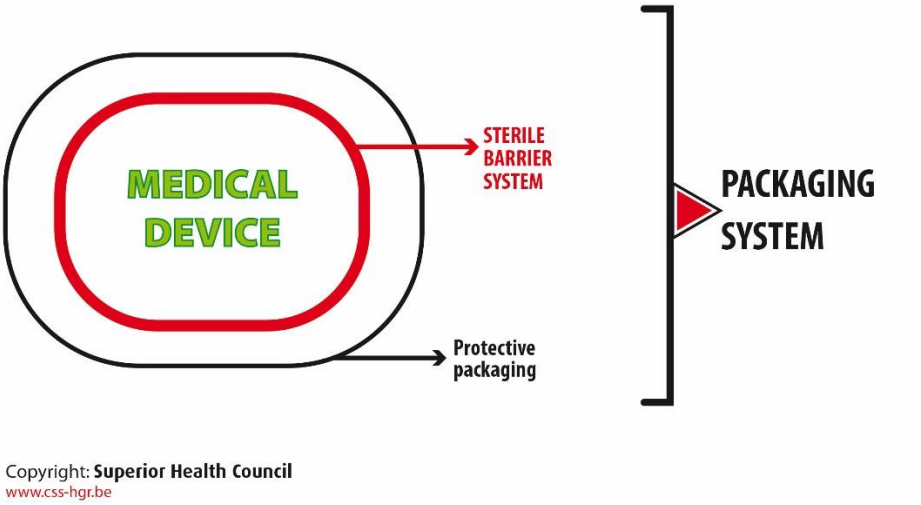
The packaging system defined in accordance with standard ISO 11607 is composed of a **sterile barrier** system (SBS) and **protective packaging**. The protective packaging will be adapted to the storage and transport conditions. The packaging system must allow the aseptic presentation of sterile MDs.

The standards organisation has published a guidance document (ISO/TS[32] 16775) to clarify the application of ISO 11607.

Standards EN 868-1 to 8 describe the requirements for packaging materials and systems.

[32] ISO TS 16775 provides guidance for the evaluation, selection and use of packaging materials: preformed sterile barrier systems, sterile barrier systems and packaging system. It also provides recommendations on validation requirements for the forming and assembly processes.

Figure 8: Packaging system



6.1.2. Application

The choice of **sterile barrier system** (SBS) must be validated. The criteria for evaluating the selection and implementation of SBS are described in ISO/TS 16775 and must be documented. The choice of protective packaging for the SBS must be subject to a risk analysis to form the packaging system.

The SBS must be permeable to air and to the sterilising agent. It must be able to undergo the chosen sterilisation process without essential modification of its characteristics.

The manufacturer of the packaging material must provide an expiry date beyond which the packaging can no longer be used. An expiry date must be affixed when the MD is sterilised.
The SBS will be equipped with a passage indicator allowing the user to verify that the MD has undergone a sterilisation process.

A class 5 (integrator) or 6 (emulator) physicochemical indicator can be added to the sterilised set.
Indicators should be considered as part of an overall sterility assurance programme and not as proof of sterility.

The label and the class 1 passage indicator of the sterilised MD must be stuck onto the SBS.

Nothing can be added to the outside of the package that could compromise the action of the sterilising agent and the maintenance of the sterile state (correct size and location of labels, no photos, nothing written or glued on the package, etc.).

A protective package for the SBS must be maintained from sterilisation to the point of use of the MD.

A requalification of the SBS and the sterilisation process is necessary when a change is made.

- packaging family: based on material composition and weight,
- packaging technology.

A change in the passage indicator that does not affect the initial validation of the packaging system does not require re-qualification.

6.2. Packaging materials and methods

6.2.1. General observations

The packaging system is adapted to the MD, the sterilisation method, the storage conditions (size of the shelves, ISO classification of the storage room, etc.), the transport conditions (open or closed carts, distances between the CSS and the storage location, etc.) and the protection of the handling staff. In this regard, particular attention will be paid to the weight and shape of the sterile set. The protective packaging must not impede the penetration of the sterilising agent or compromise the integrity of the SBS.
If the transport compromises the packaging system, additional transport packaging is recommended.

6.2.2. Packaging with sheets

Sheets can be made of crepe paper, non-woven or polypropylene, provided they meet the requirements for microbiological barriers. The sheets are provided with a batch number.

The size of the package should be adapted to the size and shape of the MD, with adequate overlap, so as to not compromise the penetration of the sterilising agent and the drying and not impede the aseptic presentation of the MD. The validated folding methods are the envelope method, the packet method (Chinese fold or parallel method) and the rolling method (Pasteur) (ISO/TS 16775-2021).

The package must be closed with a carefully applied, high quality self-adhesive tape. A passage indicator (EN 867-1 class A) is mandatory.

6.2.3. Packaging using pouches

Pouches or sheaths can be made from a combination of paper laminate, polypropylene laminate or other polymers compatible with the sterilisation method. They have a batch number.

The preferred method is to use laminated pouches with a peel-off opening. They allow the contents to be visible and the packed material to be offered aseptically.

The dimensions of the pouches must be adapted to the size and shape of the MDs. The contents must not exceed 75% of the porous area. The pouches must never be folded.

When using a second pouch as protective packaging for the SBS, the dimensions of the two pouches must be chosen such that the inner pouch can move freely in the outer pouch.

The pouch is closed by means of a calibrated and validated sealing machine. The machine must be checked daily (ISO 11607). Each weld must be checked before and after the sterilisation process.

6.2.4. Containers

Containers must be designed and validated in accordance with the standards in force: EN 868-8, ISO 11607-1 and 2, ISO/TS 16775.

Containers must be cleaned and disinfected automatically after each use. Their integrity and lack of damage must be checked after each use. They must undergo preventive maintenance in accordance with the manufacturer's specifications.

In accordance with the general requirements, the container must not be able to be opened without this being visible to the user. A suitable sealing system is used for this purpose.

6.2.5. Textile

Textiles are **not allowed** to be used for setting up a packaging system; only non-woven textiles can be used (point 6.2.2.).

7. Labelling

The label of the MD set will include **as a minimum** the identification code (see Chapter VII, point 3).

To ensure optimal traceability and facilitate the work of users, the label may also include the following elements:

- the production date,
- the name of the institution,
- the sterilisation method (via symbol or mention),
- the words or symbol "sterile if packaging is undamaged",
- the batch number,
- the expiry date,
- the name of the customer, the name of the set,
- the storage location,
- the barcode, data matrix, etc.

For reference, MDR 2017/745, Appendix I, point 23.3, describes what should be included on a sterile packaging label for the manufacturer.

X STERILISATION PROCESS

1.Saturated steam and fractional vacuum sterilization

- 1.1. Introduction
- 1.2. Principle
- 1.3. Process
  - 1.3.1. Packaging system
  - 1.3.2. Loading the sterilizer
  - 1.3.3. Phases of the cycles
    - 1.3.3.1. Preconditioning: evacuation of air and preheating
    - 1.3.3.2. Sterilisation plateau
    - 1.3.3.3. Drying
  - 1.3.4. Unloading and load release
- 1.4. Incidents
- 1.5. Checks
  - 1.5.1. Daily checks
  - 1.5.2. Permanent checks
    - 1.5.1. Check of the cycle parameters
    - 1.5.2. Cheking by means of physico-chemicals indicators
    - 1.5.3. Dryness check
    - 1.5.4. Checking of the packaging integrity
  - 1.5.3. Weekly check
  - 1.5.4. Validation

2.Sterilisation using vaporized hydrogen peroxide (VH_2O_2)

- 2.1. Introduction
- 2.2. Principle
- 2.3. Process
  - 2.3.1. Packaging system
  - 2.3.2. Loading the sterilizer
  - 2.3.3. Phases of the cycles
  - 2.3.4. Unloading and load release
- 2.4. Incidents
- 2.5. Maintenance of process efficiency
  - 2.5.1. Permanent checks
  - 2.5.2. Periodic check
  - 2.5.3. Validation or requalification

3.Other sterilisation processes

4.Special case of linen

The choice of the sterilisation process depends on the thermal resistance of the MD to be sterilised. A distinction is made between high temperature and low temperature sterilisation.

Various sterilisation methods are recognised:

- sterilisation by physical destruction processes (heat or radiation),
- sterilisation by chemical processes (gas),
- sterilisation by removal process (filtration).

Physical methods by the radiation, filtration or sterilisation of liquids are not discussed in this document.

The SHC prohibits:

- dry heat sterilisation because it cannot be checked and is not very reliable;
- ethylene oxide sterilisation in hospitals as, even if it is effective, it requires precautionary measures and a specific environment and equipment due to its toxicity.

In the current situation, only the following hospital-based MD sterilisation processes are applied in the CSS:

- sterilisation with saturated steam,
- sterilisation with vaporised hydrogen peroxide (H_2O_2).

All alternative sterilisation processes must meet the requirements of general standard ISO 14937, the main aspects of which are listed in point 3.

1. Saturated steam and fractional vacuum sterilisation

1.1. Introduction

Damp heat sterilisation using saturated steam is recommended as this process is the most reliable and easy to validate and monitor. It is therefore the **first choice** for MDs that are resistant to vacuum, moisture, high temperatures and high pressure.

1.2. Principle

The MD to be sterilised is exposed to the action of pressurised saturated steam at a given temperature and for a certain contact time.
The microorganisms are destroyed by the energy released during the condensation of the saturated steam.

Pressurised steam uses a thermodynamic balance between pressure and temperature, which must be maintained during the different phases of the sterilisation process and is only achieved if the steam is saturated (see Table 13).

Table 13: Regnault's table

Effective pressure	Absolute pressure	Temperature	Effective pressure	Absolute pressure	Temperature
Bar	Bar	°C	Bar	Bar	°C
1.00	2.013	120.42	2.00	3.013	133.69
1.05	2.063	121.21	2.05	3.063	134.25
1.10	2.113	121.96	2.10	3.113	134.82
1.15	2.163	122.73	2.15	3.163	135.36
1.20	2.213	123.46	2.20	3.213	135.88
1.25	2.263	124.18	2.25	3.263	136.43
1.30	2.313	124.90	2.30	3.313	136.98

NB: 1 bar is equivalent to 10^5 Pascal, or 100 kPa.
Absolute pressure = Patm + Peffective

1.3. Process

1.3.1. Packaging system

The packaging system must be permeable to air and steam (ISO 11607).

1.3.2. Loading the steriliser

Loading is an essential phase of the sterilisation cycle. The sterilising agent must be able to reach all the surfaces to be sterilised. The instructions given by the steriliser manufacturer must be observed during loading. The loading procedure must be integrated into the validation of the sterilisation cycle.

To avoid poor penetration of steam into the load, insufficient calorie transfer or difficult-to-check water condensation on the MD, it is strongly recommended that the maximum weight of a set not exceed 8.5 kg (EN 285, 2016).
Due to the risk of increased condensation in the load, it is recommended that heavy MDs and laminated or plastic products be placed at the bottom.
Any contact with the walls of the chamber is to be avoided.
There must be sufficient space between packaging systems (do not stack).

1.3.3. Phases of the cycle

1.3.3.1. Preconditioning: evacuation of air and preheating

The evacuation of air is an essential condition for a successful sterilisation cycle. If the air has not been completely removed, the thermodynamic balance between temperature and saturated steam pressure is disturbed and sterility can no longer be guaranteed.

For this reason, the air must be evacuated as completely as possible from the steriliser chamber by successive vacuums (fractionated vacuum), followed each time by injections of saturated steam. A vacuum level of at least 70 mbar must be achieved (EN 285).

This type of preconditioning allows the MDs to be heated and the predefined guide values for temperature and pressure to be reached in the chamber.

1.3.3.2. Sterilisation plateau

According to standard EN 285, once a thermodynamic balance has been reached for all probes, the actual sterilisation phase begins, during which the minimum guide values of the sterilisation plateau are set at:

- 15 minutes at a temperature of 121°C, which corresponds to an absolute saturated steam pressure of 2,063 mbar;
- 3 minutes at a temperature of 134°C, which corresponds to an absolute saturated steam pressure of 3,063 mbar.

1.3.3.3. Drying

At the end of the sterilisation plateau phase, the residual moisture on the MD must be removed under the combined effect of vacuum, residual heat and air intake (sterile filtered air injection).

1.3.4. Unloading and load release

The physical parameters to be measured and evaluated for parametric release are time, pressure and temperature. The parametric release of the loads is only permitted if the steriliser has been validated.
In addition to parametric release, the other permanent checks must be verified (see check point 1.5.2).
If all the checks are correct, the load can be released.
If any of the parameters are incorrect, the load must be repackaged and resterilised.

Unloading is followed by a period of acclimatisation (cooldown). MDs are only distributed once they have reached room temperature.

1.4. Incidents

The causes of non-conformity during sterilisation cycle are:

- the presence of air and non-condensable gases in the load due to insufficient air removal or a leak,
- or poor steam quality:
  - oversaturated ("wet") steam (pressure > temperature),
  - overheated ("dry") steam (pressure < temperature),
  - soiled steam (particles),
- a non-compliant temperature during the sterilisation plateau phase.

1.5. Checks

1.5.1. Daily checks

The effectiveness of the vacuum pump and the penetration of saturated steam into the sterilised load must be checked daily by a Bowie & Dick test (3.5-minute cycle at a temperature of between 134°C and 137°C).
This test is carried out at the start of production in an empty, pre-heated steriliser and after any technical intervention.

The following are used to perform this test:

- an electronic test. The SHC prefers to use these tests provided that the manufacturer can demonstrate performance with the methods described in ISO 11140-4. These tests are used to record data, monitor the performance of the steriliser and diagnose failures.
- ready-to-use test packs, if the steriliser does not allow the use of electronic testing (e.g. small steriliser). These are class 2 indicators (see Appendix 7). Bowie & Dick test packs must also meet the specifications described in EN 285, ISO 17665 (554), ISO 11140-3 and EN 867-4.
  It should be noted that these test packs were initially intended to validate the sterilisation of linen and not MDs.

If the Bowie & Dick test is not compliant, a diagnosis is performed to determine the cause of the malfunction, its impact is analysed and corrective measures are implemented.
The Bowie & Dick test must be compliant before production restarts.

1.5.2. Permanent checks

The permanent check is carried out before the load is released.
The following parameters are monitored:

- the cycle parameters: temperature, pressure and time,
- the change in physico-chemical sterilisation indicators,
- the dryness of the load,
- the integrity of the packaging.

If any of these checks are not compliant, the products are considered non-sterile.

1.5.2.1. Check of the cycle parameters

Each steriliser is equipped with a device for recording temperature and pressure as a function of time, allowing the cycle parameters to be checked. On the graph, it is essential to check the level and number of vacuums, the sterilisation plateau (temperature, pressure, time) and the drying phase. The graph should look identical to the one produced during validation.

The check of the sterilising quality of the saturated steam is based on the "pressure-temperature" ratio of Regnault's table (see Table 13). During the sterilisation plateau, the steam must have a temperature that corresponds to its theoretical steam pressure.

1.5.2.2. Checking by means of physico-chemical indicators

Class 1 indicators are used for this type of check.

These passage indicators are heat-sensitive inks on adhesive tapes or on packaging pouches. These indicators only react, and then only approximately, to temperature; they do not give any indication of time. Their change of colour only indicates that the MD has undergone a sterilisation cycle but does not guarantee the effectiveness of the process and in no way proves the destruction of all the microorganisms present (see Appendix 7).

1.5.2.3. Dryness check

Dryness is checked visually. Any damp load is declared non-compliant.

1.5.2.4. Checking of the packaging integrity

The integrity of the packaging is the only guarantee of storage in a sterile condition. Damaged packaging is declared non-compliant.

1.5.3. Weekly check

The weekly check consists of a physical check of the vacuum tightness (leak test). This test verifies the absence of leaks at the door seal, the tightness of the chamber, etc. (EN 285). Once the vacuum of less than or equal to 70 mbar has been reached, this test reveals if this vacuum is maintained at the same pressure value.

A maximum increase of 1.3 mbar/minute is allowed.

Note: check using biological indicators

The F_0 of a biological check is based on 15 min at 121°C while the F_0 of the cycles used is 60 for a 3 min cycle at 134°C and the F_0 is 360 for an 18 min cycle at 134°C (Appendix 6). Based on current knowledge and practice, the SHC believes that microbiological testing is no longer appropriate except in the case of a 121°C cycle.

1.5.4. Validation

A validation plan must be in place for all steam sterilisers. It must meet the requirements of ISO 17665 and EN 285 with IQ, OQ, PQ and routine tests (RQ/periodic tests). These mandatory periodic checks provide a guarantee of quality and compliance with good practices. This point is covered in the "Validation" chapter (Chapter VII, point 1.).

2. Sterilisation using vaporised hydrogen peroxide (VH_20_2)

2.1. Introduction

In hospitals, this sterilisation process is one of the current alternatives to low-temperature sterilisation. Until recently, this process was described in a generic standard ISO 14937, which defines the general requirements for developing, characterising, validating and routinely verifying a sterilisation process for MDs. With ISO 22441, a specific standard for describing the process, validation and routine check of VH_2O_2 is now available. EN 17180 (standard for VH_2O_2 steriliser manufacturers) and ISO 11138-6 (biological indicators for the VH_2O_2 process) will also be published between 2023 and 2024.

All the data described in the standard and resulting from the development of such a process must be documented and made available to the user by the steriliser manufacturer.

H_2O_2 sterilisation is indicated in hospitals for the sterilisation of heat-sensitive MDs. However, this method has its limitations: the nature of the MD materials, the dryness of the MDs, MDs with a light, the absence of cellulose.

In accordance with MDR 2017/745, MD manufacturers must validate and describe the H_2O_2 sterilisation process in the official IFU (instruction for use). Manufacturers are required to inform users of any changes in this compatibility.

2.2. Principle

After vacuum and preconditioning (temperature rise and drying), the MD is subjected to H_2O_2 injections followed by diffusion phases. Sterilisation results from exposure to H_2O_2 which destroys the membranes/walls of viruses and bacteria through oxidation and progressively degrades proteins. A neutralisation phase will be integrated at the end of the process. There must be no H_2O_2 residue and its removal must not present a danger to the user and the environment.

The lethal action of H_2O_2 must be proven on a representative range of microorganisms with a demonstration of their inactivation kinetics. ISO 22441 confirmed *Geobacillus stearothermophilus* as the reference microorganism and ISO 11138-1 as the standard for biological indicators. This is in anticipation of the new 11138-6 standard.

The VH_2O_2 steriliser manufacturer must provide the user with documents describing the parameters that influence the process. According to ISO 22441, pressure, temperature, time and H_2O_2 concentration are considered important variables. The user checks the efficiency of the process parametrically against the IFU of the steriliser and the MD (chamber volume, loading, material properties).

2.3. Process

2.3.1. Packaging system

The MD must be packaged in a packaging system compatible with the VH_2O_2 sterilisation method in accordance with standards ISO 11607-1, -2 and EN 868.

2.3.2. Loading the steriliser

Loading is an essential phase of the sterilisation process. The H_2O_2 must be able to reach all the surfaces to be sterilised. The instructions given by the steriliser manufacturer must be strictly observed during loading.

2.3.3. Phases of the cycle

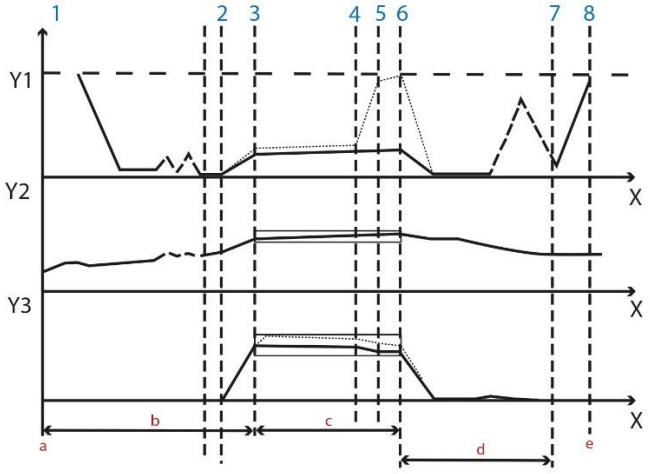
Schematically, a H_2O_2 sterilisation cycle can be represented as follows:

(1) a first vacuum carried out to remove the air from the load and create the conditions for the optimal vaporisation of the H_2O_2, (packaging phase),
(2) an injection of vaporised H_2O_2 which diffuses within the load (diffusion phase),
(3) re-pressurisation by injecting filtered air into the chamber (purification phase),
(4) a forced vacuum to remove any residual product with and finally a return to atmospheric pressure.

Phase 2 represents the sterilisation part of the cycle. Some processes repeat this one or more times to guarantee sterility, as opposed to the validation cycle for which the principle of ½ cycle is used (for which there is only one diffusion phase).

The graph below shows these elements in diagram form.

Figure 9: Example of a sterilisation cycle by VH_2O_2 (based on ISO 22441)



Y1 Pressure
Y2 Temperature
Y3 Concentration
X Time

a Start of cycle
b Conditioning stage
c Holding time
d Purging stage
e End of cycle

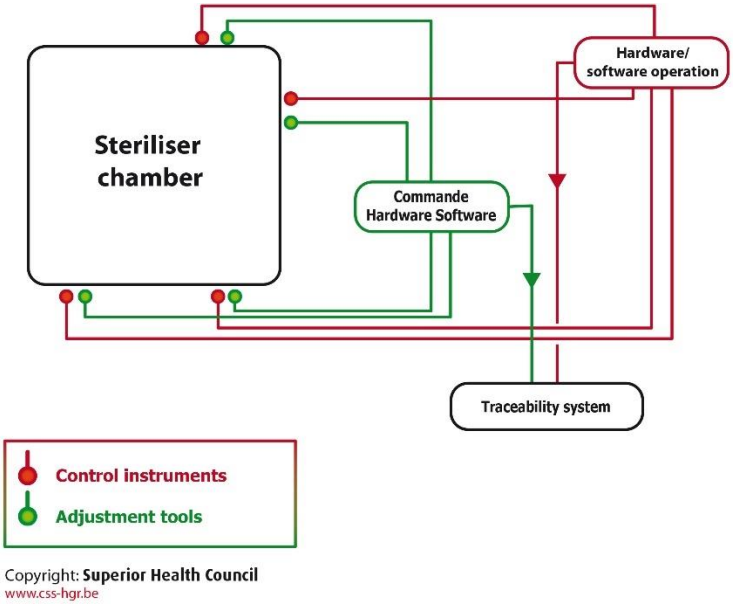
1 Start of the sterilization cycle
2 Start of exposure phase
3 Start of holding time
4 Start of air/inert gas injection pulse(s) (if applicable)
5 End of air/inert gas injection pulse(s) (if applicable)
6 End of holding time and start of purging stage
7 End of purging stage and start of air admission
8 "Cycle complete"

2.3.4. Unloading and load release

A VH_2O_2 process can be released using the parametric variables mentioned above (pressure, temperature, time and H_2O_2 concentration). The user must determine with the steriliser manufacturer how to interpret the parameters obtained. ISO 22441 indicates that biological and/or chemical indicators can be used as an additional device to release the load.

An IMS (Independent Monitoring System) is necessary to meet the requirements of the standard. The diagram below illustrates how this type of system can be set up.

Figure 10: *Independent monitoring system*



The procedure for releasing the load in this way must be defined by the steriliser manufacturer. The parameters that influence the process must be specified, checked and monitored directly. Each report must be recorded and retained.

In addition to parametric release, the efficiency of the process must be guaranteed at all times (see check point 2.5.).

2.4. Incidents

Several variables can affect the outcome:

- residual moisture that prevents the cycle from starting or ending,
- the presence of a H_2O_2 absorbing material,
- the poor diffusion of H_2O_2,
- the load is too large,
- the presence of residue on the load at the end of the cycle.

2.5. Maintenance of process efficiency

The maintenance of process efficiency must be guaranteed by:

- calibration,
- the complete periodic maintenance of the steriliser,
- requalification annually and after major interventions on the equipment,
- routine checks.

Standard ISO 22441 states that healthcare institutions are responsible for defining the procedures into which the maintenance and checks are integrated and for monitoring and recording the effective implementation.

2.5.1. Permanent check

The permanent check is carried out before the load is released.
The following are checked:

- the cycle parameters
- the change in physico-chemical sterilisation indicators,
- the biological indicators if parametric release is not possible,
- the integrity of the packaging.

If any of these checks are not compliant, the MDs are considered non-sterile.

2.5.2. Periodic check

This may involve the periodic use of biological and/or chemical indicators, PCDs. The measuring instruments of the parameters that affect the process must be calibrated regularly.

- **Biological indicators**. They must comply with standard ISO 11138-1.
- **Chemical indicators**. They must comply with standard ISO 11140-1.
- **PCD**. This must mimic the properties of an MD load that would be the most difficult to sterilise (weight, surface, materials, etc.). Chemical and/or biological indicators can be placed within the PCD to measure the achievement of sterility (ISO 11139-2018).

The steriliser should be maintained periodically in accordance with a maintenance plan agreed with the manufacturer.

2.5.3. Validation or requalification

As with any steriliser, an IQ and OQ must be performed. A PQ will then demonstrate that the steriliser is capable of providing sterile products during routine use. This point is covered in the "Validation" chapter (VII, point 1.).

3. Other sterilisation processes

For new sterilisation processes, unless a specific standard for that process has been published, a generic standard ISO 14937 defines the general requirements for routinely developing, characterising, validating and verifying an MD sterilisation process.
All the data described in the standard and resulting from the development of such a process must be documented and made available to the user by the manufacturer.
The requirements defined by this standard are the same as those described in the H_2O_2 sterilisation chapter.
The manufacturer must therefore provide the user with all the information relating to:

- the packaging system compatible with the method,
- the sterilising agent used,
- the operation of the equipment,
- the MD that can be sterilised,
- the details of the process used and, if applicable, the chemical and biological indicators or PCDs that can be used for monitoring,
- validation and routine checks,
- the release of the MD.

The device used must have been previously registered as a steriliser and as an MD by a notified body in accordance with MDR 2017/745.

If the sterilisation method has changed, the manufacturer of the re-sterilisable medical device must be consulted to ensure compatibility with the new method.

4. Special case of linen

The handling of clean, dry linen (SHC 9444, 2018) ready for sterilisation must be separeted from the MD sterilisation circuit.
Provision should be made for:

- the supply of clean linen by a specific circuit without diverting the principle of forward motion of the resterilisable MDs circuit,
- packaging the linen in a specific packaging system before it is introduced into the MD packaging area,
- the sterilisation of the linen in a steriliser that has undergone a specific check of vacuum and steam penetration within a linen load using a validated test device, ideally provided by the industry. Before reusing the steriliser for MDs, steam penetration tests must be performed on a representative load of MDs to be sterilised using a specific validated test device (see point 1.5. Bowie & Dick).

The textile packs are sterilised according to a specific and validated sterilisation cycle. This is because the textile drying phase is longer than for a standard cycle and includes more pressure variations.

XI STORAGE CONDITIONS FOR STERILE MD

1.Transport

2.Storage facilities and equipment
2.1. Central storage rooms and warehouses for sterile medical devices for operating rooms and intervention rooms
2.2. Storage in care units, medical-technical services and polyclinics

3.Conservation conditions

1. Transport

Sterile MDs must be transported from the CSS to the storage and use areas by and under the supervision of authorised staff who are trained in and aware of the criticality of the MDs transported.
The trolleys for the transport of sterile MDs must be different from those used to collect soiled MDs or must undergo machine decontamination (min A_0 60, ISO 15883-6), between the two uses.

Transport trolleys leaving the checked environment area are closed and monitored. Closed trolleys are also stored in a room, protected from external influences and only accessible to authorised persons. These transport trolleys must offer complete protection in the event of a fall in order to keep the contents inside.

During this transport, the trolleys must be equipped with pictograms to determine the nature (soiled, clean, sterile) of the MDs they are carrying. If they are transported on public roads, the requirements of the ADR[33] must be followed.

Transport conditions (temperature, humidity, integrity) have a significant impact on maintaining the sterility of sterilised MDs. These conditions must be subject to process validation based on the maintenance of the sterile state on arrival at each user site of the sterilised MD.

[33] ADR *Accord for dangerous goods by roads*

2. Storage facilities and equipment

2.1. Central storage rooms and warehouses for sterile medical devices for operating rooms and intervention rooms

These premises dedicated to the storage of sterile MDs must meet the following conditions:

- the room temperature must be between 15°C and 25°C;
- the relative humidity must be between 35% and a maximum of 65%;
- MDs cannot be in direct contact with sunlight (UV);
- these rooms are considered semi-critical zones and a pressure gradient is therefore necessary. The conditions of ISO class 8 are desirable;
- The temperature and hygrometry of the air must be monitored;
- these areas must be restricted to authorised persons;
- the transport packaging must be removed beforehand in an adjoining room (not in the operating room or the intervention rooms);
- the room must be easy to clean;
- there are no open drains or water and fluid pipes;
- the floor must be smooth, impermeable and intact;
- the room is equipped so that the MDs are not in contact with the floor (± 50 cm from the floor), walls and ceilings;
- equipment such as shelves, cabinets and transport equipment must be made of easy-to-clean materials; these must be clean and dry;
- the "first in - first out" principle must be easy to apply.

The storage and distribution of MDs must allow the rotation of the MD according to good distribution practices and the preservation of packaging integrity.

2.2. Storage in care units, medical-technical services and polyclinics

In the services, sterile medical devices are stored in locked cabinets. These cabinets are located in clean rooms with no increased risk of contamination.
The room temperature must be between 15°C and 25°C; the relative humidity should be around 60%. MDs must not come into contact with direct sunlight (UV);
The storage and distribution of MDs must allow the rotation of the MD according to good distribution practices and the preservation of packaging integrity.

3. Conservation conditions

The shelf life of sterile medical devices is determined on the basis of a risk analysis and depends on a number of factors such as the packaging material and method, the storage conditions, the number and extent of handling operations and the stability of the materials used.

Standard ISO/TS 16775 (technical sheet of ISO 11607) describes the steps necessary for validating the packaging system in healthcare facilities. The validation file must include all the information on the materials supplied by the manufacturer, on the one hand, and the tests carried out by the user in their working conditions, on the other. This file justifies the shelf life of the sterile MD as accurately as possible.

The integrity and condition of the packaging must always be checked before use.
If the integrity of the SBS is not guaranteed and it is opened outside the CSS, it must undergo a complete new cycle (cleaning/disinfection, packaging, wrapping and sterilisation). In the event of unopened packaging, the CSS manager assesses the risk and decides what process to apply.

XII MD LOAN AND IN-HOUSE MANUFACTURING

1.Loan of non-sterile MDs
- 1.1. Obligations of the supplier
- 1.2. Obligations of the hospital
- 1.3. Obligations of both parties

2.Loan of sterile MD
- 2.1. Obligations of the supplier
- 2.2. Obligations of the hospital
- 2.3. Obligations of both parties

3.Consignment

4.Testing

5.Special practices: in-house manufacturing

Since suppliers provide hospitals with MDs and several hospitals use the MDs, it is important that organisational, maintenance and NCTA[34] transmission prevention procedures are established. Each user (hospital) and the supplier agree to comply with these.

The user (the hospital) and the supplier sign an agreement that includes the provisions of European Regulation 2017/745 on MDs and with which the loan sets must comply. To clarify the rights and duties of each party, the Medical Equipment Committee (MEC) proposes an agreement that must include the information listed below. Some elements are the responsibility of the provider, others of the hospital or both.

The supplier undertakes to comply with the European directives, regulations and Belgian RD relating to MDs.

The hospital will declare any non-compliance with these texts to the FAMHP[35] using the material vigilance declaration form.

Regardless of the nature of the loan set, the hospital and supplier must ensure that:
- the sets are loaned under the express condition that they have not been used in autopsies and/or animal experiments.
- the sets are subject to traceability, allowing prevention of the transmission of NCTAs.

[34] NCTA: non-conventional transmissible agents
[35] FAMHP: Federal Agency for Medicines and Health Products

MD loans are of four types:

- the loan of non-sterile MDs: provision by the supplier of non-sterile MDs for a single medical procedure,
- the loan of sterile MDs: provision by the supplier of sterile MDs for a single medical procedure,
- consignment: long-term provision of MDs by the supplier,
- loan for a test: provision of MDs by the supplier for the duration of a test; it is treated as a short-term consignment.

1. Loan of non-sterile MDs

1.1. Obligations of the supplier

- The agreement between the two parties determines the conditions under which the reusable MDs and implants are delivered.
- The supplier must confirm the reservation of the ordered MDs by electronic transmission to the contact details previously established in the agreement.
- This confirmation includes the data provided by the hospital at the time of reservation, as well as the hospital's contact information for the MD loan supplier.
- The supplier is responsible for ensuring that the loan MD is delivered intact and complete at the agreed time and place. It guarantees that the agreed locations for the delivery of loan sets are always respected, even if delivery is made by a third party/subcontractor.
- The contents of the loan set must be made available visually clean and decontaminated. Cleaning and decontamination are documented at the time of delivery. The purpose of this provision is to allow the hospital to ensure the protection of its employees under the conditions provided for by the Law of 4 August 1996 and the RD of 4 August 1996 on the protection of workers against risks related to exposure to biological agents at work.
- The MDs on loan must be delivered in clean, closed transport packaging in accordance with the applicable standards and guidelines (ADR).
- The transport containers must be clean, washable and closed, with comfortable handles (with enough space for fingers). If these containers are delivered stacked, the handles of the upper containers must not exceed 140 cm in height (the guidelines on this subject can be found in ISO 11228-1 and at www.ergonomiesite.be/arbeid/gewicht_tillen.htm).
- The supplier must accurately identify the loan set (name, usage and unique device identifier (UDI)). This UDI must allow hospital traceability software to identify each set on loan.
- The supplier must identify the components of the set with clear, up-to-date photos/images that respect the proportions and dimensions of the components.

- The supplier must provide the staff who take charge of and/or use the loan set with the instructions for use in the national languages of the country[36], specifying:
    - information on appropriate reuse procedures, including cleaning, disinfection, packaging, and the sterilisation method if the MD is to be resterilised, and any restrictions on the number of times the MD can be reused,
    - detailed assembly and disassembly procedures illustrated by a diagram or photo,
    - the content of the information provided corresponding to what is specified in ISO 17664,
    - references to the standards, guidelines and processes applicable in Belgium are mentioned.
- The supplier undertakes to ensure that the user can apply the appropriate cleaning and sterilisation methods.
- The supplier is responsible for the functionality, integrity and maintenance of each MD and also checks it before dispatch. If the set is exceptionally to be used for two medical procedures, the supplier ensures the functionality and integrity of each MD.
- MDs that are part of the loan must be delivered in a flat-bottomed, stainless steel basket.
    - stainless steel mesh must have no sharp or protruding edges or feet and must be of DIN[37] or ISO or derived size (maximum L x W x H: 54x25x13);
    - stainless steel mesh must be able to guarantee proper cleaning, disinfection and sterilisation at all times.
- If the MD is presented in packaging other than a stainless steel basket, the hospital transfers the contents to a basket that meets the above requirements.
- The contents of a set must have a maximum weight of 8.5 kg (ISO 11228-1 and NBN-EN 1005-1). If instructions on how the MD must be positioned have been affixed to the basket base plate, the MD or test prosthesis/implant name and measurement number must be updated.
- The supplier agrees that all MDs that are part of the loan will be CE-marked and that the products involved comply with all the applicable legislation, including MDR 2017/745.
- In the exceptional case of several uses of a loan set in the same hospital, single-use MDs must be replaced by the supplier between each use.

[36] Article 9, §1 of the Law of 22 December 2020

[37] DIN: *Deutsches Institut für Normung*

- The following information accompanies the MD loan and/or is digitally transmitted in advance to the contact information provided at the time of reservation:
    - the delivery document with a unique reference number, number of packages, name of surgeon (or authorised requester), and scheduled procedure date. If the contents of the set differ, this is indicated in the delivery document;
    - an up-to-date list of the contents, photos of each set and the correct reference number of each MD;
    - non-sterile implants delivered are accompanied by a list of references and quantities and, if possible, all the important additional information (batch number, expiry date, notification or identification code, price, etc.);
    - instructions on cleaning, disinfection and sterilisation requirements;
    - a completed and signed decontamination form for delivery;
    - the supplier's contact information.

1.2. Obligations of the hospital

- The MD reservation must be as precise as possible; it must include at least the name of the MD requested and the date and time of the intervention. The name of the surgeon must also be mentioned.
- The loan set received is considered as a contaminated MD; standard precautions apply.
- The hospital checks the loan set against the delivery note.
- The cleaning, disinfection and sterilisation of the sets are performed in the CSS and must take place before use. The same requirements as for hospital MDs apply to the loan set.
- The cleaning and disinfection of loaner sets after patient use should be performed in the CSS prior to their return to the supplier.
- The hospital ensures that the loaned sets comply with the delivery on their return.
- The collection location(s) are defined in advance between the hospital and the supplier. The hospital notifies the supplier of any changes in a timely manner.
- It is the responsibility of the hospital to ensure that the MD loan is ready for collection no later than 24 hours after the end of the procedure, complete with all accessories, all cleaned and disinfected. The opening hours of the CSS should be taken into account.
- For each loan of MDs, the hospital confirms cleaning and decontamination on return using a decontamination form. The purpose of this undertaking is to allow the supplier to ensure the protection of its employees under the conditions provided for by the Law of 4 August 1996 and by the RD of 4 August 1996 on the protection of workers against risks related to exposure to biological agents at work.

1.3. Obligations of both parties

- The loan set must be delivered at least 24 hours (CSS opening hours) before the intervention, within working hours, and be returned at most 24 hours after the intervention, unless otherwise agreed.
- For exceptional and urgent loans for an unforeseeable intervention, the supplier and the CSS manager agree on the delivery terms.

2. Loan of sterile MD

2.1. Obligations of the supplier

The contents of the loan set can also be delivered sterile if this has been agreed with the supplier. In this case, the supplier bears full responsibility for the compliance of the devices (systems and treatment packs) that it places on the market and for the associated sterility. Here too, it can be agreed that sterilisation is justified by a document accompanying the visual shipment.

- The agreement between the two parties determines the conditions under which the reusable MDs and implants are delivered.
- The supplier must confirm the reservation of the ordered MD by electronic transmission to the contact details previously established in the agreement.
- This confirmation includes the data provided by the hospital at the time of reservation, as well as the hospital's contact information for the MD loan supplier.
- The supplier is responsible for ensuring that the loan MD is delivered intact and complete at the agreed time and place. It guarantees that the agreed locations for the delivery of loan sets are always respected, even if delivery is made by a third party/subcontractor.
- Reusable MDs and implants are supplied sterile. The supplier (the company issuing the equipment on loan) must provide proof of correct sterilisation.
- The MDs on loan must be delivered in clean, closed transport packaging in accordance with the applicable standards and guidelines (ADR).
- Transport containers for sterile implants must allow delivery to the operating room in accordance with hospital hygiene regulations (SHC 8573, 2013). Tertiary packaging is not permitted in the operating room.
- The supplier must accurately identify the loan set (name, usage and unique device identifier (UDI)). This IUD must allow hospital traceability software to identify each set on loan.
- The supplier must identify the components of the set with clear, up-to-date photos/images that respect the proportions and dimensions of the components.
- The supplier must provide the staff who use the loan set with the instructions for use in the national languages of the country[38], specifying:
    - the content of the information provided, corresponding to what is specified in ISO 17664.
    - in the user manual, only references to the standards, guidelines and processes applicable in Belgium are mentioned.
- The supplier is responsible for the functionality, integrity and maintenance of each MD and also checks it before dispatch. If the set is exceptionally to be used for two medical procedures, the supplier ensures the functionality and integrity of each MD.
- The contents of a set must have a maximum weight of 8.5 kg (ISO 11228-1 and NBN-EN 1005-1). If instructions on how the MD must be positioned have been affixed to the basket base plate, the MD or test prosthesis/implant name and measurement number must be updated.

[38] Article 9, §1 of the Law of 22 December 2020

- The supplier agrees that all MDs that are part of the loan will be CE-marked and that the products involved comply with all the applicable legislation, including MDR 2017/745.
- In the exceptional case of several uses of a loan set in the same hospital, single-use MDs must be replaced by the supplier between each use.
- The following information accompanies the MD loan and/or is digitally transmitted in advance to the contact information provided at the time of reservation:
    - the delivery document with a unique reference number, number of packages, name of surgeon (or authorised requester), and scheduled procedure date. If the contents of the set differ, this is indicated in the delivery document;
    - an up-to-date list of the contents, photos of each set and the correct reference number of each MD;
    - sterile implants delivered are accompanied by a list of references and quantities and, if possible, all the important additional information (batch number, expiry date, notification or identification code, price, etc.);
    - a completed and signed sterilisation form and release report for loan MDs;
    - the supplier's contact information.

2.2. Obligations of the hospital

- The MD reservation must be as precise as possible; it must include at least the name of the MD requested and the date and time of the intervention. The name of the surgeon must also be mentioned.
- The hospital checks the loan set against the delivery note.
- The hospital checks that the packaging guaranteeing the sterility of the MD is intact.
- The collection location(s) are defined in advance between the hospital and the supplier. The hospital notifies the supplier of any changes in a timely manner.
- It is the responsibility of the hospital to ensure that the MD loan is ready for collection no later than 24 hours after the end of the procedure.

2.3. Obligations of both parties

- The loan set must be delivered at least 24 hours (CSS opening hours) before the intervention, within working hours, and be returned to the supplier at most 24 hours after the intervention, unless otherwise agreed.
- For exceptional and urgent loans for an unforeseeable intervention, the supplier and the CSS manager agree on the delivery terms.

3. Consignment

Consignment must be the subject of an agreement or contract between the supplier and the hospital.
The supplier retains ownership of the products it makes available to the hospital. The even temporary return of the MD by the supplier puts an end to the consignment contract. Any long-term release is subject to a new contract or consignment agreement.

Prior to delivery of the consigned MD, the supplier ensures that they meet the conditions established by the hospital institution and provides, as a minimum:

- the certificate issued by the notified body,
- the declaration of conformity,
- the list of the components of the set (name, reference, UDI, expiry date) in the national languages of the country or in English,
- the leaflet containing recommendations for the management of the MD in accordance with ISO 17664; the supplier ensures that its recommendations comply with these good practices and are provided in the national languages of the country or in English.

4. Testing

The supplier and the hospital agree on the terms and conditions of the test in an agreement. The conditions for depositing the MDs are the same as those for a deposit on consignment, with the difference that the end of the test is defined beforehand.

The test is scheduled for a minimum of three MD management procedures to allow the CSS manager to issue an opinion on these conditions.

The MD drop-off occurs one week prior to the scheduled start of the test to allow the CSS manager and the supplier to ensure the proper management of the MD, the feasibility of the manufacturer's planned treatment procedures (ISO 17664), and the compliance of the MD with MDR 2017/745.

5. Special practices: in-house manufacturing

In-house MD manufacturing (3D printing) is covered by Art. 5 of MDR 2017/745. These MDs can only be manufactured if they are unique and not commercially available; the hospital then takes on a manufacturer's responsibility.

XIII SINGLE-USE MEDICAL DEVICES

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostics constitute the basic legal framework for MDs.

Their purpose is both to ensure a high level of protection of the health and safety of people and the functioning of the internal market.

Regulation 2017/745 contains the following definition for
"single-use device": *a device that is intended to be used on one individual during a single procedure*.

Article 17 of this regulation describes the reprocessing of single-use MDs. Such reprocessing may only take place where permitted by national law and only in accordance with Article 17.
Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 as regards common specifications for the reprocessing of single-use devices, describes in detail how compliance with Article 17 of Regulation 2017/745 can be achieved.

Belgium has chosen to allow reprocessing if compliance with the Implementing Regulation 2020/1207 and thus with Regulation 2017/745 can be demonstrated to a notified body. This notified body can then certify the processing facility.
This is described in Section 6 of Article 12 of the Law of 22 December 2020 on medical devices and Chapter 3 Article 6 of the RD of 12 May 2021 implementing the Law of 22 December on medical devices.

Reprocessing can be selected by an external reprocessing company that complies with the current regulations and legislation.
The choice can also be made to perform the reprocessing in their own care facility, in compliance with Article 17 of MDR 2017/745 and the Implementing Regulation of 2020/1207.

This Implementing Regulation 2020/1207 describes, among other things:

- the obligation to notify the FAMHP of any reprocessing: whether this reprocessing takes place in its own care facility or with an external reprocessing company,
- the requirement to implement a quality system for reprocessing activities if the hospital wants to perform reprocessing,
- the return of MDs originally from the healthcare facility if the user works with an external reprocessing company (Article 24),
- the requirement for patient-friendly notification,
- all the practical aspects, the procedures and the reprocessing steps.

XIV SUBCONTRACTING

1. Legal framework

The RD of 30 September 2020 on the preparation and dispensing of drugs and the use and distribution of medical devices in healthcare facilities describes how the hospital pharmacist can outsource the sterilisation of MD. Article 22 of this RD was repealed by the RD of 23 December 2021 and reinstated by the RD of 31 May 2022. It mentions the following text:

Art. 22 §1. The hospital pharmacist may subcontract the sterilisation of medical devices to

1° another hospital pharmacist in a hospital pharmacy that has the appropriate facilities and equipment for the performance of sterilisation and that they have validated for that purpose;

2° a holder of a preparation authorisation as referred to in Article 12, § 1/1 of the Law of 25 March 1964 on medicines, whose authorisation is valid for the sterilisation of medical devices (Art. 1, 1°, RD 31/05/2022).

The facility and equipment referred to in the above-mentioned article must comply with the principles and guidelines for the sterilisation of medical devices, as listed in Annexes IIa and IIb of the RD of 30 September 2020 (Art. 1, 2°, RD of 31 May 2022).

The outsourcing hospital pharmacist and the hospital pharmacist or holder of the preparation authorisation to whom the preparation or sterilisation of medical devices is delegated must establish a collaboration agreement that contains at least the following:

1° adequate measures for the technical and organisational measures
on the protection of patient data transmitted in the framework of the outsourcing,

2° a clear description of the duties and responsibilities of each party,

3° a clause according to which the hospital pharmacist or the holder of the preparation authorisation to whom the outsourcing is entrusted acts only on the instructions of the hospital pharmacist who entrusts the outsourcing and, in their capacity as data controller, acts exclusively on the instructions of the data controller and may only process data for the purposes for which they have been informed and may not provide data to third parties (Art. 1, §2, RD 31/05/2022).

The hospital pharmacist who subcontracts, communicates at least the following data to the hospital pharmacist or the person in charge of the authorisation holder from whom they request the sterilisation of medical devices:

1° the name of the hospital pharmacist requesting the subcontracting, and the address and telephone number of the hospital pharmacy,

2° the date of the request,

3° the indication of the type of sterilisation (Art. 1, §3, RD 31/05/2022).

The hospital pharmacist or the person responsible for the authorisation-holder to whom the sterilisation of medical devices is delegated, draws up a protocol in duplicate. A copy of the protocol he(she) has signed is provided with the result of his/her work to the hospital pharmacist who requested the subcontracting (Art. 1, §4, RD 31/05/2022).

This protocol mentions at least the following data:

1° the name of the hospital pharmacist or of the person in charge of the preparation authorisation holder who establishes the sterilisation and the address and telephone number of the hospital pharmacy or of the authorisation holder
2° the sterilisation date,
3° the indication of the type of sterilisation,
4° the checks carried out and the available data on the expiry date,
5° the precautionary measures to be taken, including measures for storage, handling, use and transport.

The protocol is kept at the pharmacy for at least ten years after delivery so that none of the stored data is lost.

The protocol is defined in the RD as a written or electronic document describing the procedure, that specifies the operations to be performed, the precautions to be taken and the checks to be carried out in relation to the sterilisation of medical devices.

Agreements with other partners are essential as part of a hospital emergency plan.

2. Recommendations

Under the above-mentioned legislation, the subcontracting of certain activities, including the sterilisation of medical devices, may be carried out between hospital pharmacists or between a hospital pharmacist and the holder of a preparation authorisation for the sterilisation of medical devices.

The hospital pharmacist can subcontract this activity if he(she) does not have the appropriate equipment. Of course, this may or may not be due to a momentary lack of capacity to ensure the entire production.

The protocol between the two parties must be made contractual. In particular, it complies with the regulations on subcontracting and the transport of infectious materials (FPS Mobility and Transport, 2015, ADR).

This protocol between the two parties must also be established, taking into account the management of unforeseen events (e.g. damage to the packaging MD, drop of MDs, delays).

XV NON-CONVENTIONAL TRANSMISSIBLE AGENTS (NCTA)

A review of the literature was carried out to establish recommendations on the management of MDs in potential contact with NCTAs. This review is included in Appendix 8 of these recommendations.

Traceability is an **essential** tool in preventing the transmission of NCTAs.
The management of these patients and MDs must be the subject of a procedure set up at the institutional level.

If the CSS is notified of (1) a patient with Creutzfeldt – Jakob disease (CJD) or (2) a patient at high risk or suspected of having CJD who has undergone a transmission risk procedure (see table in Appendix 8), it should:

- not use the ultrasound bath (aerosolisation),
- perform prion inactivation (see point 1.3., Appendix 8) of the invasive MD at risk of transmission,
- quarantine (under seal, in a closed area) the MD until the patient's NCTA status is confirmed
  - CJD confirmed: MD destruction/incineration
  - CJD disproved: complete MD sterilisation process.

In these cases, it is recommended that a risk analysis also be performed to identify patients and other potentially contaminated MDs (cross-contamination) and that a vacuum cycle with total WD inactivator is performed.

If the CSS is notified of a patient at high risk or suspected of having CJD but who has not undergone a risky procedure, the routine cleaning, disinfection and sterilisation of the device should be performed.

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XVII APPENDICES

1. Appendix 1: Legal Framework

1.1. Regulation

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- **EN 868-3:** Packaging for terminally sterilized medical devices - Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods. 2017.
- **EN 868-4:** Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods.2017.
- **EN 868-5:** Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods.2018.
- **EN 868-6**: Packaging for terminally sterilized medical devices – Part 6: paper for low temperature sterilization processes – Requirements and test methods.2017.
- **EN 868-7:** Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods.2017
- **EN 868-8**: Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods. 2018.
- **ISO 8674**: Hexagon high nuts (style 2) with metric fine pitch thread — Product grades A and B. 2012
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- **ISO 11140-5**: Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests. 2007.
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- **ISO 14937**: Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices. 2009.
- **ISO 15223-1:** Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements. 2016.
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2. Appendix 2: Unit of work

The unit of work is a calculation method that takes into account the complexity and number of MDs that make up the instrument sets. The table for calculating activity, costs and staffing is available on the website of the professional associations ASTER[39] and VSZ[40]. Below are the "composition data" and "accounting data" tables as examples.

ONGLET DE SAISIE DES PRODUITS

DISPOSITIFS MEDICAUX STERILISES A LA VAPEUR

SERVICES	COMPOSITIONS	Coefficient de pondération	Nombre de Compositions	Nombre d'UO
BLOCS OPERATOIRES	Nombre de compositions stérilisées à l'unité (1DM/sachet)	15		0
	Nombre de compositions stérilisées comportant de 2 à 10 DM	30		0
	Nombre de compositions stérilisées comportant de 11 à 60 DM	110		0
	Nombre de compositions stérilisées comportant plus de 60 DM	160		0
	Nombre de compositions stérilisées comportant des DM en prêt	160		0
	Nombre de compositions spécifiques et particulières	120		0
	Nombre de compositions décontaminées sans stérilisation	7		0
CONSULTATIONS, POLYCLINIQUES, MEDICO TECHNIQUE, SALLE D'ACCOUCHEMENT et FAUTEUILS DENTAIRES hors Bloc	Nombre de compositions stérilisées à l'unité (1DM/sachet)	15		0
	Nombre de compositions stérilisées comportant de 2 à 10 DM	30		0
	Nombre de compositions stérilisées comportant de 11 à 60 DM	110		0
	Nombre de compositions décontaminées sans stérilisation	7		0
SERVICES DE SOINS	Nombre de compositions stérilisées à l'unité (1DM/sachet)	10		0
	Nombre de compositions stérilisées comportant au moins 2 DM	15		0
	Nombre de compositions décontaminées sans stérilisation	7		0
	Pour les D.M., nombre d' UO Ste calculé avec les coefficients affecté aux catégories de compositions détaillées.	**0**		

[39] ASTER: Belgian French-speaking association for the sterilisation of medical devices
[40] VSZ: Vereniging *Sterilisatie* in het Ziekenhuis

LINGE				
TOUTES LES CATEGORIES D'UTILISATEURS	Nombre de compositions de linge stérilisées à l'unité ou en pack	10		0

DISPOSITIFS MEDICAUX STERILISES A BASSE TEMPERATURE				
TOUTES LES CATEGORIES D'UTILISATEURS	Nombre de compositions comportant des DM sans canal opérateur	80		0
	Nombre de compositions comportant des DM avec canal opérateur	160		0

VEUILLEZ REMPLIR LE NOMBRE DE COMPOSITIONS DE LINGE DANS LA CELLULE BLEUE

		LINGE A SAISIR MANUELLEMENT	
Total des UO Ste vapeur (détaillées et simplifiées).	0		0
Total des UO Ste pour la stérilisation Basse Température	0		

SYNTHESE

Total des UO Ste vapeur	0
Total des UO Ste vapeur et UO S.B.T.	0

Données comptables

Merci d'introduire les coûts qui sont imputés ou imputables au service de stérilisation.
Les coûts doivent doivent être en **négatif**
Les recettes doivent être en **positif.**

Catégorie	Nom	Imputation directe (code 160 stérilisation)		imputation indirecte ou semi directe				
		Code	Coûts	Code	clef de répartition	cout total indiect	% imputable	cout imputable à la stérilisation
PERSONNEL (coûts et recouvrement)								
Personnel infirmier et autres fonctions								
	Personnel infirmier	617, 620, 623, 624,625						
	Personnel infirmier stagiaires							
	Personnel infirmier contractuel subsidié							
	Soutien logistique au personnel infirmier							
	Personnel infirmier Maribel							
	Direction infirmière et cadre intermédiaire							
	Personnel intérimaire							
	Paramédical et salarié							
	Personnel indépendant	619						
	Autres fonctions							
	Recouvrement d'autres frais de personnel	7431						
	Recouvrement Maribel	7432						
	Recouvrement pour le personnel	7092						
Total du Personnel infirmier et autres fonctions			- €					- €
TOTAUX charges & recouvrement du PERSONNEL								- €
ACHATS								
Achats produits pharmaceutiques								
	Achats de produits pharma	600						
	- Produits courants							
	- Linge stérile à usage unique							
	- Prescriptions magistrales (anticeptiques,…)							
	…							
	Autres							- €
Total du Achats produits pharmaceutiques			- €					- €
Achats autres produits médicaux								
	Achats produits méd. non stériles	601						
	- Disposables et petit matériel							
	- Matériel injection - perfusion							
	- Matériel de prélèvement							
	Autres							- €
Total du Achats autres produits médicaux			- €					- €
Achat de fournitures diverses								
	Achats fournitures diverses	602						
	Autres							- €
Total du Total du Achats autres produits médicaux			- €					- €
Achats de produits et petit matériel pour l'entretien								
	Produits et petit matériel d'entretien	603						
	- Produits et petit matériel de nettoyage							
	-Produits de lessive							
	- Produits de vaisselle							
	- Divers produits et petit matériel d'entretien							
	Autres							- €
Total du Achats de produits et petit matériel pour l'entretien			- €					- €
	Fournitures de bureau	605						
	- Petit mobilier							
	- Fournitures informatiques							
	- Achats bureau et infor - Divers							
	Autres							- €
Total du			- €					- €
Achat linge litterie, buanderie,								
	vêtements de travail	606			kgs linge			- €
	Autres				kgs linge			- €
Total du Achat linge litterie, buanderie,			- €					- €
Energie et chauffage								
	Energie	6040 et 6041			en m²			- €
	Eau	6042			en m²			- €
	Autres				en m²			
Total du Energie et chauffage			- €					- €
Nettoyage et entretretien des locaux								
	Services de nettoyage extérieur	61131			en m²			- €
	Services de nettoyage	selon vos données comptables sur base du temps passé			en m²			- €
	Autres				en m²			
Total du Nettoyage et entretretien des locaux			- €					- €
Transport et logistique								
	Transport réalisé par un tiers	6120			en m²			- €
	Transport réalisé en interne	selon vos données comptables sur base des transports ré			en m²			- €
	Autres				en m²			
Total du Transport et logistique			- €					- €
TOTAUX ACHATS								- €

IMMOBILIER,EQUIPEMENT,MOBILIER								
Entretien des locaux								
	maintenance de l'immobilier	61310/61320			en m²			- €
	réparation de l'immobilier	61311 à 61319 61321 à 61329			en m²			- €
	Maintenance des ascenseurs	61330			en m²			- €
	réparation des ascenseurs	61331 à 61339			en m²			- €
	maintenance des installations de chauffage et	61340			en m²			- €
	réparation des installations de chauffage et	61341 à 61349			en m²			- €
	Sur grosses réparations et gros entretiens	63024			en m²			- €
	Amortissements reconditionnnement	63025			en m²			- €
	Autres				en m²			- €
Total du Entretien des locaux			**- €**					**- €**
Equipement								
	maintenance des équipements médicaux	61350						
	réparation matériel médical	61351 à 61359						
	Amortissement équipement médical	6303						
	Location du matériel	selon vos données comptables						
	Subsides en investissements (remonter aux coû	753						
	Autres							- €
Total du Equipement			**- €**					**- €**
Matériel, matériel mobile, informatique								
	maintenance du mobilier & des équipements	61370						
	réparation du mobilier et des équipements non-	61371						
	Ammortissement du mobilier	6304						
	Autres							- €
Total du Matériel, matériel mobile, informatique			**- €**					**- €**
TOTAUX CHARGES ENTRETIEN et AMORTISSEMENT								**- €**

AUTRES CHARGES								
contrat de service								
	sous-traitance de stérilisation (tous services)	6118*						- €
	INTERETS EMPRUNTS	6500						- €
	Autres							- €
Total du contrat de service			**- €**					**- €**
Autres								
	Autres							- €
Total du Autres			**- €**					**- €**
TOTAUX CHARGES AUTRE								**- €**

AUTRES RECETTES (sous-traitance, autres)								
recettes des prestations								
	Sous traitance	709						
	Autres							- €
Total du recettes des prestations			**- €**					**- €**
Autres								
	Divers	744 à 749						- €
Total du Autres			**- €**					**- €**
TOTAUX RECETTES AUTRE								**- €**

Charges totales service de stérilisation centralisé pour l'institution	- €

3. Appendix 3: Useful information for checking water quality

Below are various tables that are useful for checking water quality: microbiological parameters and possible contaminants.

Parameters and parametric values - Part A: microbiological parameter

(Annex 1, Directive 98/83/EC)

Parameters	Parametric value (number/100 ml)
Escherichia coli (E. Coli)	0
Enterococci	0

Water sold in bottles or containers must comply with the following values:

Parameters	Parametric value
Escherichia coli (E. Coli)	0 / 250 ml
Enterococci	0 / 250 ml
Pseudomonas aeruginosa	0 / 250 ml
Colony content at 22 °C	100 / ml
Colony content at 37 °C	20 / 20 ml

Contaminants in the feed water of a dedicated steam generator

(EN 285)

Determinant	Feed water
Residue on evaporation	≤ 10 mg/l
Silicate	≤ 1 mg/l
Iron	≤ 0,2 mg/l
Cadmium[a]	≤ 0,005 mg/l
Lead[a]	≤ 0,05 mg/l
Residual heavy metals except iron, cadmium and lead	≤ 0,1 mg/l
Chloride[b]	≤ 2 mg/l
Phosphate	≤ 0,5 mg/l
Conductivity (at 25°C)[c]	≤ 5 µS/cm
pH (at 20°C)	5 tot 7,5
Appearance	Colourless, clean and without sediment
Hardness (Σ alkaline earth ions)	≤ 0,02 mmol/l
Note that it is possible to check conformity according to known analysis methods	
[a] the limit values meet the requirements for drinking water [b] the maximum chloride concentration in the feed water, combined with high temperatures, affects corrosion. [c] refer to the European Pharmacopoeia	

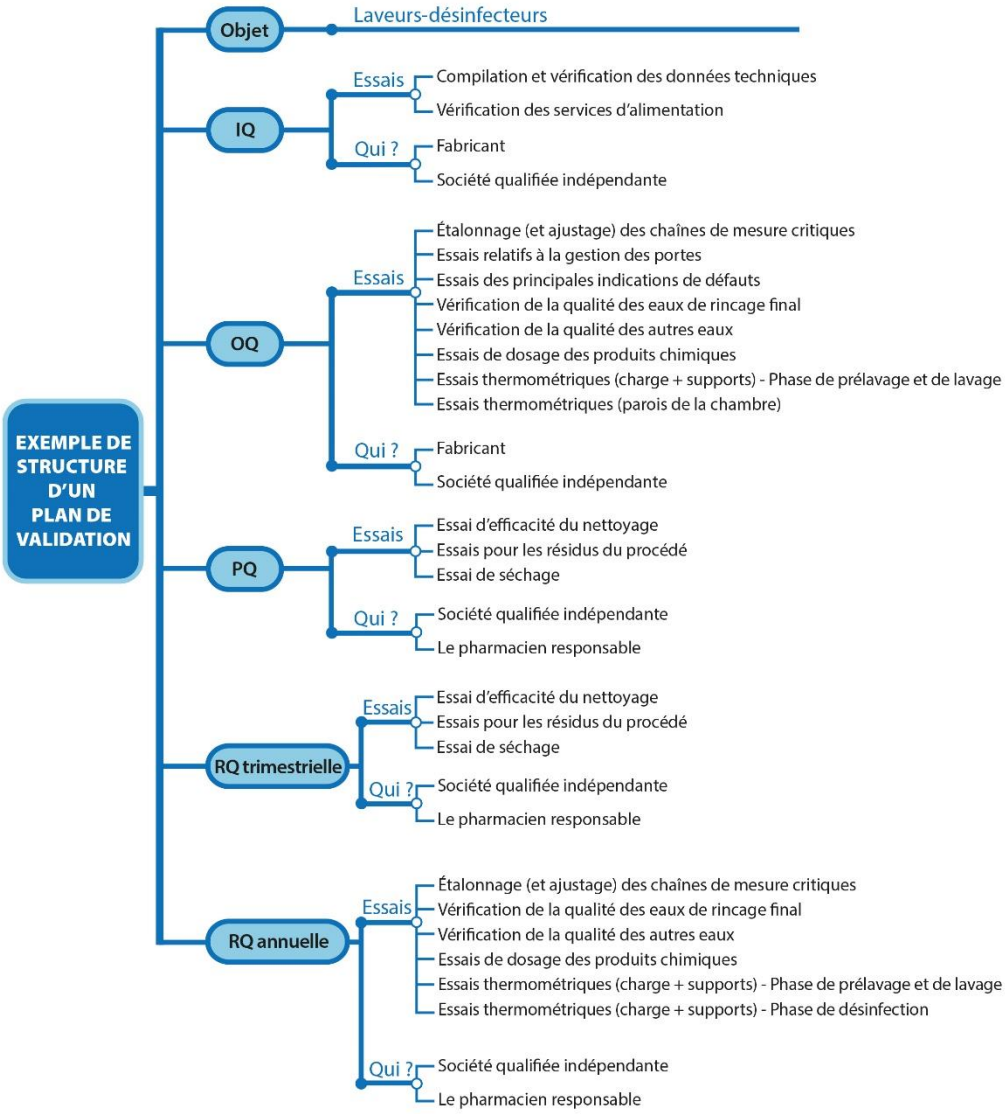
Contaminants present in the condensate measured in the steam supplied to the steriliser to be considered in relation to the corrosion of materials (Table A.1., EN 285)

Determinant	Condensate
Silicate (SiO_2)	≤ 0,1 mg/l
Iron	≤ 0,1 mg/l
Cadmium[a]	≤ 0,005 mg/l
Lead[a]	≤ 0,05 mg/l
Residual heavy metals except iron, cadmium and lead	≤ 0,1 mg/l
Chloride (Cl^-)[b]	≤ 0,1 mg/l
Phosphate (P_2O_5)	≤ 0,1 mg/l
Conductivity (at 25°C)[c]	≤ 3 µS/cm
pH (acidity)	5 tot 7
Appearance	Colourless, clean and without sediment
Hardness (Σ alkaline earth ions)	≤ 0,02 mmol/l
Note that a method for taking a condensate sample is explained in EN 285: 2006, 22.4.	

Contaminants present in the condensate of the steam supplied to the steriliser to be considered in relation to the contamination of the load (Table A.2., EN 285)

Determinant	Clean condensate
Acidity or alkalinity	R[a]
Ammonium (NH_4)	≤ 0,2 mg/l
Calcium and magnesium	R[a] (mg/l)
Heavy metals	≤ 0,1 mg/l
Chloride (Cl^-)	≤ 0,5 mg/l
Nitrate (NO_3)	≤ 0,2 mg/l
Sulphate (SO_4)	R[a] (mg/l)
Oxidisable substances	R[a]
Evaporation residue	≤ 30 mg/l
Silicate (SiO_2)	≤ 0,1 mg/l
Phosphate (P_2O_5)	≤ 0,1 mg/l
Conductivity (at 25°C)	≤ 35 µS/cm
Bacterial endotoxins	≤ 0,25 EU/ml
Appearance	Colourless, clean
[a] reagent test specified in the European Pharmacopoeia Note: a method for taking a condensate sample is explained in EN 285: 2006, 22.4.	

4. Appendix 4: example structure for a validation plan



5. Appendix 5: FMECA method

One method of evaluating potential failures can be the FMEA method (**F**ailure **M**ode, **E**ffects and **C**riticality **A**nalysis).

This method always involves a **qualitative** analysis:

- root **cause** analysis;
- failure **mode** analysis;
- failure **effect** analysis;

Then a **quantitative** evaluation:

- evaluation of the **frequency of occurrence** of these failures;
- evaluation of the **severity** of these failures;
- evaluation of the **probability** of these failures going undetected.

It is important to include all potential stakeholders (technical, CSS staff, customers and management) in this sterilisation risk analysis.
A simple way to measure the criticality of an event is to perform the following calculation:

C = G x F x D

With:
C: Criticality
G: Severity
F: Frequency
D: Detection

This calculated criticality rate allows the corrective or preventive measures to be taken as a priority to be chosen, with a collective vision and the consensus of the different parties concerned.

6. Appendix 6: Calculations of the sterilisation value F_0 and the disinfection value A_0

6.1. Calculation of the sterilisation value F0 and equivalence of cycles for saturated steam sterilisation

The **biological indicator** chosen to validate saturated steam sterilisation uses *Bacillus stearothermophilus* spores of reference strains (ATCC 12980 pe) (Galtier, Eur. Pharmacopoeia).

Values of this reference strain: $D_{120°C}$ = 1.5 min; Z= 10°C
Number of germs at the start: 10^6

In accordance with the two laws of sterilisation:

1. $D_{120°C}$ =1.5 min means that it takes 1.5 min to destroy 90% of the germs present at 120°C.

With a contamination of 10^6 germs, it will take 6 x 1.5 min = 9 min to obtain 1 germ.
Since the SAL[41] is 10^{-6} (SAL means the probability of finding 1 germ in 10^6), it will take another 6 x1.5 min to reach this SAL.
Conclusion: At 120°C, it will take 18 min to change the contamination from 10^6 to the SAL.

2. Z= 10°C means that if the temperature increases by 10°C, the time needed to kill the same number of germs is 10 times shorter (Arrhenius' law). $D_{130°C}$ = 0.15 min

To compare cycles at different temperatures and evaluate their equivalence, it is necessary to bring the durations back to the reference temperature: the **lethality rate L** is used to do this.

"L" is the relationship between the sterilisation effectiveness of a treatment at a given temperature compared to that of a treatment at the reference temperature, either 120°C (UK) or 250°F (121.1°C US)

At 120°C, L= 1 (Anglo-Saxon table, AS)	At 120°C, L= 0.774
At 121°C, L= 1.25	A 121°C, L= 1 (US table 250 °F)
A 130°C, L=10	A 131°C, L= 10
A 134°C, L= 25	A 134°C, L= 20

Sterilisation value F_0: the time in minutes during which sterilisation takes place at a temperature of 120°C (AS) or 121°C (USA), with a thermal destruction value of Z = 10°C, to obtain a sterilising effect.

Note: check in the sterilisers' programmes whether they use the Anglo-Saxon or American reference to calculate F_0.

[41] SAL: Sterility Assurance Level

Calculation of the sterilisation value of several cycles compared to the reference cycle:
Reference cycle:

18 min at 120°C is equivalent to 15 min at 121°C, i.e. F_0 = 18 min (AS) or 15 min (USA)

1 min at 120°C is equivalent to 1/25= 0.04 min at 134°C
1 min at 134°C is equivalent to 25 min at 120°C or 20 min at 121°C
3 min at 134°C is equivalent to 75 min at 120°C or 60 min at 121°C
18 min at 134°C (prion cycle) is equivalent to 450 min at 120°C or 360 min at 121°C

6.2. Calculation of the disinfection value A_0 and equivalence of the thermal disinfection cycles.

Since the F_0 concept is used to determine the sterilising value, ISO 15883 has incorporated the A_0 concept for thermal disinfection.

Thermal disinfection value A_0: this is the time in seconds during which disinfection takes place at a temperature of 80°C, with a thermal destruction value of Z = 10°C, to obtain a disinfection effect.

$$A_o = 10^{\frac{(T-80)}{Z}} * \Delta t$$

Z = 10°C (thermal destruction factor)
T = observed temperature
Δt = time interval (seconds)

The table below lists a number of temperatures and the corresponding times that can be used to achieve reliable thermal disinfection.

Guide values for temperature and contact time for thermal disinfection.

Temperature in °C	A_0 = 600		A_0 = 3,000	
	Time in seconds	Time in minutes	Time in seconds	Time in minutes
80	600	10	3,000	50
90	60	1	300	5
93	30	0.50	150	2.5

When it is stated that the MD must be disinfected with an **A_0** of 600, this means that a disinfection plateau must be maintained for 600 sec (= 10 min) at 80°C or 60 sec (=1 min) at 90°C.

Similarly, if an **A_0** of 3,000 is to be applied, this means that the disinfection plateau must be maintained for 3,000 sec (= 50 min) at 80°C or 300 sec (= 5 min) at 90°C.

7. Appendix 7: Indicators

The chemical indicators or indicator systems described in Part 3 of ISO 11140 are intended for use in the following main applications:

a) to allow differentiation between units that have undergone treatment and those that have not;
b) in specific tests and/or processes, for example the Bowie-Dick test;
c) placement inside the individual load units to assess whether the process parameter(s) have been achieved and whether the respective parameter(s) have been achieved at the location where they were placed.

The six types of indicators described in the main body of this part of ISO 11140 are divided into different categories according to their performance requirements. The table below provides a description of three categories based on their intended use. The chemical indicators in each of these categories are also subdivided according to the sterilisation process for which they were designed. These categories have no hierarchical meaning. If the end point of the chemical indicator has been reached, this should not be interpreted as an indication that an acceptable SAL level has been achieved, but rather as one of many factors to be considered when evaluating the acceptability of a sterilisation process.

Categories according to intended use

Intended use		**Class**	**Category**	**Description (intended use)**
Indicate exposure to a process in order to differentiate between units that have been treated and those that have not, and/or indicate a significant failure of a sterilisation process		1	e1	"Exposure" or process indicator Requirements according to class 1
Indicators for use in special applications, e.g. Bowie-Dick type test		2	s2	"Special" indicator (e.g. Bowie-Dick) Requirements according to ISO 11140-3, ISO 11140-4 and ISO 11140-5.
Indicators to be placed inside the individual load units and intended to evaluate the achievement of the critical process variables at the location they have been placed	This indicator reacts to only one critical process variable	3	i3	"Internal" indicator Single variable indicator Requirements according to class 3
	This indicator reacts to more than one critical process variable	4	i4	"Internal" indicator Multiple variable indicator Requirements according to class 4
	This indicator reacts to all the critical process variables	5	i5	"Internal" indicator Integrating indicator Requirements according to class 5
	This indicator reacts to all the critical process variables	6	i6	"Internal" indicator Emulation indicator Requirements according to class 6

Class 1: process indicators
Process indicators are intended for use with individual units (e.g. packs, containers) to indicate whether the unit has been directly exposed to the sterilisation process and distinguish between units that have been processed and those that have not. They must be designed to respond to one or more of the critical process variables.

Class 2: Indicators for use in specific tests
Class 2 indicators are intended for use in specific test processes as defined in the relevant standards for sterilisers/sterilisation.
Note: the requirements for specific test indicators (class 2 indicators) are included in other sections of ISO 11140.

Class 3: Single variable indicator
A single variable indicator should be designed to react to one of the critical variables and is intended to indicate exposure to a sterilisation process based on an established reference value for the selected variable.

Class 4: Multiple variable indicator
A multiple variable indicator should be designed to react to two or more of the critical variables and is intended to indicate exposure to a sterilisation cycle based on established reference values for the selected variables.

Class 5: Integrating indicators
Integrating indicators must be designed to respond to all critical variables. The reference values are set to be equivalent to or better than the performance requirements defined in the ISO 11138 series of standards for biological indicators.

Class 6: Emulation indicators
Emulation indicators are used to monitor sterilisation cycles and must be designed to respond to all critical variables for accurate sterilisation cycles. The reference values are established on the basis of the critical variables of the sterilisation process in question (NEN-EN-ISO11140-1 standard).

8. Appendix 8: Non-conventional transmissible agents (NCTA - prions)

8.1. Introduction

The risk of transmission of transmissible spongiform encephalopathies (TSEs) depends primarily on the category of the patient and the nature of the tissue handled.

The worldwide incidence of Creutzfeldt-Jakob Disease (CJD) is approximately 1/1,000,000. Most patients present with rapidly progressive dementia accompanied by focal neurological symptoms, including ataxia, myoclonus, visual disturbances, and rigidity. Death usually occurs within four to six months of symptom onset (GOV UK, 2012).

At-risk patients are those with clinical symptoms consistent with TSE and patients at risk after medical treatment with brain substances/transplants or with first-degree relatives with CJD. A more detailed description of this risk group can be found in SHC Advisory Report 7276-2 (2006).

The tissues with the highest infectivity are those that contact and/or originate from the central nervous system, including the brain, spinal cord, retina, optic nerve (SHC No. 7276-2, 2006), posterior surface of the lens, choroid, pituitary gland, spinal ganglia, and olfactory epithelium (Swissnoso, 2019); the dental nerve is not considered to be of high infectivity (WHO, 2003).

The presence of abnormal proteins is distributed over a larger number of tissues, depending on the type of CJD. In variant CJD, abnormal proteins are additionally found in the tonsils, spleen, appendix, rectum, lymph nodes, adrenals, thymus and gut-associated lymphoid tissue, whereas in the sporadic form, these proteins are found primarily in the central nervous system (Peden et al., 2006). The infectious agency of blood remains questionable (Ritchie et al., 2015; Swissnoso, 2019).

In practice, sporadic CJD is diagnosed on the basis of clinical suspicion and according to the ECDC definition[42]. Since 2016, the number of brain biopsies in living patients has been systematically reduced to virtually zero with the introduction of the RT-QuIC (Real Time Quaking Induced Conversion) test in cerebrospinal fluid. Brain biopsies performed with single-use MDs have their limitations, in part because of the problem of infection transmission and decontamination, and in part because of limited sampling options.

This RT-QuIC is a biochemical test that detects the pathological prion protein (PrPsc). A positive RT-QuIC result almost always means prion disease is present, with a specificity of 99%. However, a negative RT-QuIC does not exclude diagnosis. The first-generation RT-QuIC tests currently in use in Belgium have a sensitivity of 85%. Second-generation RT-QuIC tests use truncated recombinant PrP instead of full-length recombinant PrP and have a higher sensitivity (95%). The first-generation analysis technique gives results after 4.5 days, but a positive signal can be obtained after just 40 to 60 hours. A neuropathological examination usually takes 3 to 5 weeks.

[42] ECDC: European Centre for Disease Prevention and Control https://medialibrary.uantwerpen.be/files/138954/47d8056e-c12d-4f82-a93c-87f41723fcd4.pdf?_ga=2.149707446.1274573121.1653654748-856972024.1625135084

8.2. Risk of prion transmission via MDs

In view of the very long incubation time of these diseases, the traceability of the MDs used on each patient is essential (see Chapter VII, point 3).

In the event of suspicion, clear procedures must be created and implemented in healthcare institutions to allow everyone to put in place specific measures.

Invasive procedures should be performed only when necessary in patients at high or moderate risk of CJD (SHC 7276, 2006). A brain biopsy should be avoided in those with a probable TSE. However, if it is necessary, the stereotactic approach and the pneumatic cranial perforator should be avoided.

According to the World Health Organization (WHO, 2003), the following procedures are considered risky:

- in neurosurgery, with the opening of the dura mater, excluding the spine (risk of effraction of the dura mater considered accidental and rare),
- in ophthalmology, procedures affecting the retina or optic nerve,
- in otorhinolaryngology surgery or endoscopy, procedures involving the olfactory mucosa
- only in a patient with or suspected of having the new variant of CJD: invasive surgical procedures with contact, biopsy or curettage of a lymph node or organised lymphoid formation, procedures involving the respiratory tract (intubations or use of laryngeal masks, endoscopies, ultrasounds), endoscopies via the rectal route.

It is strongly recommended to use **a single-use MD**.
However, care should be taken to ensure that the quality of this MD is equivalent to that of reusable MDs (ESAC-Pr, 2007).

If the use of single-use MDs is impossible, the standard prion protocol available on the ANSM website[43] (Standard Prion Protocol v2018 - ANSM - sante.fr) may be applied, taking the necessary protective precautions for staff. Some of these products are available on the Belgian market and can be used for this purpose. Attention should be paid to the availability of MDs and possible delays in treating other patients if reusable MDs must be destroyed or quarantined. Surgical staff should indicate whether a set of reusable MDs can be reconfigured so that the entire set of MDs is not destroyed or quarantined (ANCJDR, 2013[44]).

[43] ANSM: *Agence nationale de sécurité du médicament et des produits de santé* [National Agency for Medicines and Health Products Safety] (France) https://ansm.sante.fr/vos-demarches/industriel/protocole-standard-prion-v2018
[44] https://www1.health.gov.au/internet/main/publishing.nsf/Content/icg-guidelines-index.htm

Summary of MD management according to patient status and surgical procedure

	High-risk tissue (brain, spinal cord, dura mater, olfactory epithelium)	**Low-risk tissue**
CJD patients	Single use and incinerate or Prion inactivation	Single use and incinerate or Prion inactivation
Patients with high risk or suspected CJD*	Single use and incinerate or Prion inactivation with quarantine: - if CJD positive, incinerate. - if CJD negative, re-circulate through the full sterilisation process.	Routine cleaning/disinfection and a complete sterilisation process
Patients without CJD	Complete MD sterilisation process.	Complete MD sterilisation process.

*Includes symptomatic patients and patients at increased risk due to genetic CJD, dura mater recipients, recipients of human-derived pituitary hormones or growth hormones, corneal transplant recipients, recipients of blood from patients who subsequently had CJD, iatrogenic CJD (e.g. via a blood donor, contaminated plasma products between 1990-2001, underwent intradural brain surgery and intradural spine surgery prior to 1992), persons who may have come into contact with surgical instruments used in high-risk tissues where the patient may have been contaminated with CJD.

8.3. Prion inactivation

Prions are resistant to common disinfection and sterilisation processes.
This is why it is called prion **inactivation**. Inactivation is defined as a treatment that reduces the infectivity of the treated MD and treatment fluids. Inactivation is "complete" when infectivity is no longer detectable by reference methods.
No process by itself guarantees the absolute inactivation of prions and thus the completely safe treatment of the MD (SHC 7276-2, 2006).

In patients with no clear diagnosis of CJD at the time of neurosurgical intervention, MDs should be treated in the same manner as MDs used in procedures involving patients with suspected or confirmed CJD (see above).

If the MDs have not been used on the brain, spinal cord or eye, they can first be subjected to ultrasound in a closed ultrasound machine, then machine cleaned and disinfected and sterilised thermally (134°C/18 minutes or six consecutive cycles at 134°-137°C with a minimum hold time of 3 minutes). Neutral or enzymatic detergents compatible with the device can be used.
After this special treatment, the ultrasound bath and the washer-disinfector (WD) must run a vacuum cycle to decontaminate them. Solid waste must be disposed of by incineration. Fluids must be disposed of safely, either by normal direct WD disposal or by collection and inactivation (Canadian Directive, NHS UK Directive[45]).

[45] https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group specific in Annex E

The current inactivation modalities and conditions may be modified according to the evolution of knowledge and the updating of recommendations.

It is necessary to check with the manufacturer of the reusable MD that the treatment process is compatible with the nature of the device. If the reusable device used in a prion-risk procedure does not withstand the total inactivation process, it is destroyed. The complete destruction of infectivity can only be guaranteed by incineration at a temperature above 800°C.

Depending on the risk, reusable medical devices sent for repair, overhaul or maintenance, on loan or returned from loan, must first have undergone the complete sterilisation procedure and be accompanied by the information attesting to the treatment carried out. The traceability of procedures, the MD, and the different stages of MD processing must be ensured.

No cross-contamination via cleaning and disinfection equipment has been demonstrated at this time. As a precautionary measure, the SHC recommends washing vacuum equipment with one of the available inactivating products (see ANSM list[46]).

8.4. Transport of the MD concerned

The MD must be transported to the CSS **immediately**. Research has shown that the residual amount of proteinaceous material increases significantly when surgical MDs are stored for longer than 15 minutes under dry conditions (ACDP TSE, 2012).

8.5. Quarantine measures

Once inactivation has been achieved, the patient's MDs are quarantined until the patient's status is confirmed.
If the diagnosis is ruled out, the MD can be reused after a standard sterilisation process.
If the diagnosis is confirmed, the MDs are destroyed.

8.6. Look-back procedure

If a patient has been exposed to an MD that was previously used on high-risk tissue from a patient who later found to have CJD, this should be reported to the Chief Medical Officer and notified to Sciensano.

A risk analysis must be performed to assess how far the reversal procedure should go. In this risk analysis, the possible contamination of the equipment (WD, steriliser) and of the MDs that have been in the same processing cycle must be taken into account.

The way of communicating with patients who need to be contacted as a result of this turnaround procedure is determined in advance.

[46] https://ansm.sante.fr/vos-demarches/industriel/liste-des-produits-inactivants-et-format-de-dossier-pour-la-revendication-de-performances-dinactivation

This shows the importance of a tracking system for reusable MDs, so that as few patients as possible are affected by a possible reversal.

8.7. Loan set

Suppliers must provide a form with the loan indicating the status of the last patient and whether the treatment was as expected in accordance with the instructions.

XVIII COMPOSITION OF THE WORKING GROUP

The composition of the Committee and that of the Board as well as the list of experts appointed by Royal Decree are available on the following website: About us.

All experts joined the working group ***in a private capacity***. Their general declarations of interests as well as those of the members of the Committee and the Board can be viewed on the SHC website (site: conflicts of interest).

The following experts were involved in drawing up and endorsing this advisory report. The working group was chaired by **Patricia Brosens**; the scientific secretary was **Muriel Baltes**.

BROSENS Patricia	Hospital pharmacy, sterilisation	Pensioner
DE LA CHARLERIE Isabelle	Nursing, sterilisation	ASTER, Jolimont
DELHAUTER Blaise	Hospital pharmacy, sterilisation	CHR Citadelle Liège
DE MAITER Guido	Nursing, hospital hygiene	AZ Groeninge, network nursing
DREESEN MIRA	Hospital pharmacy, sterilisation	UZ LEuven
FREDERIC Sandrine	Nursing, sterilisation	*Cliniques Universitaires Saint-Luc Bruxelles*, ASTER
HENROTIN Krist	Nursing, sterilisation	UZ Gent
HOUDART Natacha	Nursing, sterilization, infection prevention and control	*Groupe Jolimont*
MEERT Wouter	Nursing, sterilisation	UZ Leuven
ONSEA Thomas	Hospital pharmacy, sterilisation	ZNA
SCHOLTES Sophie	Hospital pharmacy, sterilisation	ULB Erasme
SWITTEN Nathalie	Hospital pharmacy, sterilisation	Jessa ziekenhuis
VANDENDRIESSCHE Sigurd	Nursing, sterilisation	*Cliniques de l'Europe Bruxelles*
WILLIEME Olivier	Nursing, sterilisation	CARE-NAM *Namur*

The following experts peer reviewed the advisory report but did not take part in endorsing it:

DE JONGHE Pieter Jan	Hospital pharmacy, Radio-pharmacy	AZ Groeninge, Kortrijk
EVEN Alain-Michel	Nursing, sterilisation	*Groupe Vivalia* Libramont, ASTER
GABRIEL Bart	Psychiatric Nursing, sterilisation	AZ Maria Middelares, Gent
HUYSMANS Anja	Nursing, sterilisation	AZ Sint-Maarten, Mechelen
POTVLIEGE Catherine	Medical microbiology	Pensioner
RENSON Michel	Nursing, sterilisation	*Hôpitaux Iris-sud Molière-Longchamps, ASTER*

The following administrations and/or ministerial cabinets were heard:

HALEWYCK Hadewych	FAMHP
LOGNOUL Bernard	FAMHP

This advisory report was translated by an external translation agency.

About the Superior Health Council (SHC)

The Superior Health Council is a federal body that is part of the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides scientific advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC takes no decisions on the policies to follow, nor does it implement them. It does, however, aim at giving guidance to political decision-makers on public health matters. It does this on the basis of the most recent scientific knowledge

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, members of scientific institutions), 200 of whom are appointed experts of the Council. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, and a Committee on Professional Conduct) as well as the final endorsement of the advisory reports by the Board (ultimate decision-making body of the SHC, which consists of 30 members from the pool of appointed experts). This coherent set of procedures aims at allowing the SHC to issue advisory reports that are based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

The advisory reports drawn up by the working groups are submitted to the Board. Once they have been endorsed, they are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.shc-belgium.be), except as regards confidential advisory reports. Some of them are also communicated to the press and to target groups among healthcare professionals.

The SHC is also an active partner in developing the EuSANH network (European Science Advisory Network for Health), which aims at drawing up advisory reports at the European level.

In order to receive notification about the activities and publications of the SHC, you can send a mail to info.hgr-css@health.belgium.be .

www.shc-belgium.be

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