Superior
Health Council

GOOD PRACTICES FOR THE STERILISATION OF MEDICAL DEVICES

REVISION OF THE RECOMMENDATIONS ON STERILISATION (SHC 7848 – 2006)

MAY 2017
SHC No. 9256

.be

Superior Health Council

GOOD PRACTICES FOR THE STERILISATION OF MEDICAL DEVICES

REVISION OF THE RECOMMENDATIONS ON STERILISATION (SHC 7848 – 2006)

MAY 2017
SHC No. 9256

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

They describe 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.

.be

Federal Public Service Health, Food Chain Safety and Environment

Superior Health Council
Place Victor Horta 40 bte 10
B-1060 Bruxelles

Tel.: 02/524 97 97
E-mail: info.hgr-css@health.belgium.be

Please cite this document as follows:
Superior Health Council. Good practices for the sterilisation of medical devices - Revision of the recommendations on sterilisation (SHC 7848 – 2006). Brussels: Superior Health Council; 2017. Report 9256.

Public advisory reports as well as booklets may be consulted in full on the Superior Health Council website:
www.css-hgr.be

Superior Health Council

PUBLICATION OF THE SUPERIOR HEALTH COUNCIL No. 9256

Good practices for the sterilisation of medical devices
Revision of the recommendations on sterilisation (SHC 7848 – 2006)

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

They describe 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 in
May 2017[1]

I SUMMARY

Paradoxically, patients are at greatest risk of infection in hospitals. The sterilisation of medical devices (MD) is an important component in the fight against healthcare-associated infections.

Diagnostic and therapeutic medical and surgical techniques are constantly evolving, and the use of sterile MDs plays an increasingly important role in this area. The sterilisation techniques used in hospitals are also constantly evolving, and the sterilisation of reusable MDs is carried out in the Central Sterilisation Department (CSD), or can be outsourced. With this in mind, the Superior Health Council (SHC) considered it necessary to update the "Recommendations on sterilisation techniques" that were issued in 1993 and revised in 2006.

The aim of this document is to provide care institutions and external sterilisation partners with a guide to *good practice* that describes the necessary steps for the proper handling of MDs and for preserving their sterility until used.

After a brief introduction about the organisation of the CSD, the importance of cleaning and disinfection methods for soiled MDs prior to sterilisation is explained. It provides an explanation of and justification for the main recommended sterilisation methods, such as the sterilisation by physical (e.g. saturated steam) and chemical (e.g. hydrogen peroxide(H2O2)) means.

[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.

The qualifications, validation standards and routine checks are presented for each of the devices used in the central sterilisation department. There are also recommendations regarding the packaging, transportation, storage and shelf life of sterile MDs as well as the infrastructure of the premises.

Several chapters are also devoted to loan sets, as well as to the issue of resterilising and reusing single-use MDs and that of unconventional transmissible agents (UTAs - prions). Finally, the traceability of sterile MDs is discussed against the background of the implementation of a quality system in the sterilisation process.

In conclusion, the publication, dissemination and implementation of these good practices will enable the healthcare sectors to optimise sterilisation practices in the interest of all healthcare providers as well as patient safety.

II CONTENTS

III INTRODUCTION AND SCOPE OF THE RECOMMENDATIONS

1 Introduction

Techniques and practices in the CSD are evolving, and the SHC believes in this regard that the "Recommendations for Sterilisation Techniques" from 1993, revised in 2006, must be updated, since previous versions of the recommendations are now out of date or incomplete.

According to the Royal Decree (RD) of 26 April[2] 2007, the hospital hygiene team must ensure implementation of guidelines and recommendations issued by official bodies, such as the SHC.

The SHC recommendations are a practical guide for both the managements of care institutions and the staff of sterilisation departments, and for the administration in connection with inspections and accreditations.

With this publication, the SHC is targeting the dissemination and practical application of these recommendations, and an improvement in quality at healthcare institutions, for the benefit of the patient.

Other methods or innovative techniques are allowed as long as they are performed according to validated methods and appear to be qualitatively equivalent.

2 Scope

The recommendations include good practices relating to the sterilisation and preservation of sterility until use of:

- sterilisable MDs for use in the hospital;
- MDs used in connection with the removal of organs and human bodily material (HBM) for human use;
- instruments on loan;
- implantable non-sterile MDs.

Processes that are not used in hospitals, such as radiation sterilisation using gamma rays or electron accelerators, are not included here.
Specific techniques such as the "autoclaving" of waste are also not discussed, because the purpose of these methods differs from that of the methods used in the CSD.

The instruments used on animals, for autopsies and cadaver sessions, must be clearly separate from those for clinical use, and must not be handled in the CSD. Contaminated laboratory equipment is also not sterilised in the CSD.

The sterilisation of liquids has not been included in the recommendations, as this is a pharmaceutical compound.

[2] 26 APRIL 2007. Royal Decree amending the Royal Decree of 23 October 1964 laying down the standards to be complied with by hospitals and their services.

It is proposed that the handling of endoscopes (HGR 8355, 2010) and linen (HGR 8075, 2005) be left outside these recommendations, since they are already the subject of specific opinions from the SHC that continue to be applicable.

Keywords and MeSH *descriptor terms*[3]

MeSH (Medical Subject Headings) is the NLM (National Library of Medicine) controlled vocabulary thesaurus used for indexing

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

articles for PubMed http://www.ncbi.nlm.nih.gov/mesh.

[3] 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".

IV METHODOLOGY

Having assessed the request, the Board and the Chairman of the study group identified the expertise needed. An ad hoc study group was subsequently established with experts in the following disciplines: hospital pharmacy, nursing, hospital hygiene, sterilisation, microbiology and prions. The study group experts submitted a general and an ad hoc declaration of interests. The potential for a conflict of interests was assessed by the Committee for Deontology and Ethics. Representatives of the Federal Agency for Medicines and Health Products (FAMHP) were also consulted.

The opinion is based on existing regulations (annex 1), scientific literature, reports from national and international organisations competent in this area (peer reviewed) as well as the assessment of the experts.

Once approval of the opinion by the study group, it was finally validated by the Board.

List of abbreviations used

ACDP TSE	Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy
CJD	Creutzfeldt-Jakob disease
CSD	Central Sterilisation Department
EO	Ethylene oxide
FAMHP	Federal Agency for Medicines and Health Products
SHC	Superior Health Council of Belgium
IMS	Independent monitoring system
IQ	Installation qualification
RD	Royal Decree
MD	Medical devices
HBM	Human bodily material
MSA	Multisystem atrophy
OQ	Operational qualification
TSE	Transmissible spongiform encephalopathies
PCD	Process Challenge device
PQ	Performance qualification
SAL	Sterility assurance level
WHO	World Health Organization

V GENERAL

1 Sterilisation

The SCD may only handle MDs as described in the RD of 18/03/1999[4] (e.g. the CE marking). The use of reusable MDs implies the application of documented treatment regulations.
MDs can be divided into three groups according to use and the risk of transmission of infectious agents: non-critical, semi-critical and critical MDs. The Spaulding classification[5] serves as a common thread through the applicable maintenance procedures:

- non-critical (in contact with intact skin): clean carefully, disinfect and dry, where necessary;
- semi-critical (contact with mucous membranes or slightly damaged skin): clean carefully, disinfect, dry and if necessary sterilise;
- critical (contact with sterile tissue or sterile cavities): clean carefully, disinfect, dry. Proper sterilisation afterwards is mandatory.

The MDs handled in the CSD are mostly critical MDs, and are therefore sterilised after sufficient cleaning and disinfection.

Objectives
The purpose of cleaning is to remove visible and invisible contaminants.

The purpose of disinfection is to reduce the bioburden.

Sterilisation covers a range of processes that result in the sterility of the treated MDs. Sterility is defined as the absence of viable micro-organisms on these MDs. The purpose of sterilising an object is therefore to kill or irreversibly immobilize micro-organisms present in or on that object, so that the chance of survival does not exceed one micro-organism per million (10^{-6}) units treated (European Pharmacopoeia 8.0, point 5.1.1.). This status must be maintained until the MD is used.

Since it is not possible to verify the sterility of MDs with tests on the end product, it is essential to validate the procedures and equipment and to continue to monitor all procedures through checks. Prior and correctly validated cleaning and disinfection procedures are vital to guarantee effective sterilisation.

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

- the staff framework,
- the use of adapted infrastructure and adapted ambient conditions (ventilation, pressure, humidity, etc.),
- the use of reusable MDs,
- compliance with the required hygiene precautions to reduce the bioburden prior to sterilization,

[4] RD of 18 March 1999: Royal Decree on medical devices
[5] "Spaulding's Classification of Medical Equipment/Devices and Required Level of Processing/Reprocessing", found on page 15 of the document "Best Practices for Cleaning, Disinfection, and Sterilization in All Health Care Settings" (see annex B, [7]) The Role of chemical disinfection in the prevention of nosocomial infections (see annex B, [11]).

- the development of validated methods for all critical production steps,
- supervision of the working environment,
- the use of good storage conditions,
- the use of a quality assurance system.

2 Practical organisation of sterilisation

2.1 Centralisation of sterilisation activities

Central management of sterilisation activities in the hospital is mandatory.
Processes are to be carried out under reproducible and validated protocols.

The CSD is an autonomous medical and technical department, independent of the operating theatre, where all the necessary resources and skills are present. It is located such that logistics processes run as smoothly as possible, with a clear division of contaminated and sterile MDs.

Centralisation guarantees standardisation of procedures along with more effective management, conducted under the supervision of and by qualified staff who receive ongoing additional training.

Sterilisation according to good practice takes at least 4 hours.

2.2 Legal framework

The RD of 23 October 1964[6] laying down the standards to be complied with by hospitals and their services (II design and operation of each type of service, identification letter C organisational standards 2°) states that:

"The sterilisation of instruments and bandages must be carried out impeccably, by means of reliable installations that are available for use at all times. Evidence of suitability must be kept at the disposal of the inspection authorities.

The service must have competent staff available at all times for the operating room and for sterilisation.
The surgery department must include: a designated sterilisation room."

The RD of 15 December 1978 determines the special standards for university hospitals and hospital services (Annex 5, chapter XI):
"The hospital must have a central sterilisation service. 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.

[6] 23 October 1964. - Royal Decree laying down the standards to be complied with by hospitals and their services

All sterilisation equipment must be concentrated in the CSD. This principle may only be waived for the rapid sterilisation equipment of the operating theatre or similar services (e.g. intensive care) and for the gas sterilisation equipment used for precision instruments.

The CSD shall have a dirty, clean and sterile zone.

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

Daily activities shall be monitored by a hospital doctor or by the hospital pharmacist, designated by name.

Daily activities shall be carried out under the supervision of a nurse, designated by name. A nurse must be present during each sterilisation."

The RD of 4 March 1991 laying down the standards to be met by a hospital pharmacist in order to be accredited (Chapter III Functional standards art. 12) states that:
"The hospital pharmacist must ensure the quality of daily activities relating to central sterilisation by:

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

2.3 Staff framework

The **hospital pharmacist**, designated by name as the person responsible for the CSD, must ensure the quality of daily activities relating to central sterilisation as set out in the RD of 4 March 1991.

Operational changes may not be made without the prior consent of the hospital pharmacist.

A **senior nurse** shall be appointed and present for the daily operation and coordination of the CSD. The SHC recommends specific training in CSD management, recognised by the administration.

Sterilisation staff shall at least have a basic secondary vocational education.

The SHC recommends that **staff** receive specific training in sterilisation techniques, recognised by the administration.
Continuous training is necessary, especially when implementing amended or new processes.

Supervision by a sterilisation expert (member of staff with specific training in sterilisation) is necessary for each sterilisation process.

The release of sterile MDs forms part of a procedure. In case of doubt, only the department head and/or the hospital pharmacist may make a decision regarding release. In the absence of the above, the MDs shall be placed in quarantine or reprocessed.

Staff numbers in the CSD must be proportional to the number and nature of surgical interventions and other activities in the hospital.
The service's work schedule shall be adapted according to the work load, the hospital activity and the available trained staff.

It is recommended that technical staff be appointed to maintain and repair the equipment in the CSD. This person or these persons must have received specific training at the manufacturers for use of the CSD equipment.

Ideally, the staff responsible for implementing and maintaining IT and tracing systems shall have been trained.

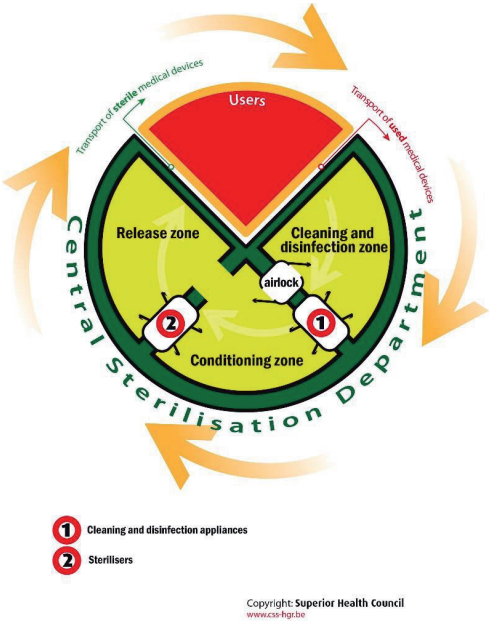
All procedures must be approved by the Committee for Hospital Hygiene (RD, 26/04/2007).

3 Flow

When designing, equipping and organising the CSD, intersection of the various flows must be prevented via (people and MDs):

- different zones with access procedures for the separate treatment of dirty, clean and sterile MDs;
- observance of the principle of forward flow for MDs (dirty, clean, sterile);
- limiting access to authorised persons;
- observance of basic hygiene rules (such as hand hygiene, general prevention rules, clothing, etc.) for staff and visitors.

Figure 1: Description of the flow of MDs in the hospital



3.1 Architectural design

The area of the service allows the rooms to be separated and the principle of forward flow to be observed with space for the appropriate equipment and the necessary supplies (consumables). The required area must be adapted to the activities, the equipment and the organisation of the work. A minimum area of 250 m² is recommended.

The architectural design must ensure distinction between three zones[7]:

- the cleaning and disinfection zone: sorting, cleaning and disinfection of MDs and transport systems;
- the conditioning zone: checking, putting together, packing, sterilising;
- the release zone: checking release, cooldown, storage.

For staff, the cleaning and disinfection zone on the one hand and the conditioning zone and release zone on the other constitute two different entities.
Access is via an airlock specifically for the cleaning and disinfection zone and an airlock for the conditioning zone and release zone.

[7] For clarification, the designation of the zones in these recommendations has been modified compared with the RD KB of 1978

Air control

There are no regulations covering the required values for air quality in the CSD. Canadian accreditation[8] requires a clear separation of the different work zones, a minimum of 10 air changes per hour and a positive pressure in relation to the cleaning and disinfection zones. Most of Belgium's neighbouring countries (namely France, Switzerland, the Netherlands, Germany, England) recommend at least the characteristics of class ISO 8[9] "at rest" in the conditioning zone with the check carried out in accordance with the provisions of ISO standard 14644-1. They regard this (low) requirement level "at rest" as essential to also ensure sufficiently good air quality during "activity".

It therefore seems reasonable to recommend the characteristics of class ISO 8 at rest in the conditioning zone with periodic checks, especially in the context of new installations or renovations.

To achieve ISO 8, appropriate refreshing of treated air is required (at least 15 air changes per hour in accordance with the recommendations of AFS 2002). The air supply shall consist of (at least) 20 % fresh air. To guarantee an overpressure of at least 15 Pa (NF S 90-351), an airlock must be provided between the cleaning and disinfection zone on the one hand and the conditioning zone on the other. The two doors cannot be opened at the same time.

Ideally, the pressure within the CSD should be distributed as follows:

- maximum overpressure (30 Pascal) in the conditioning zone of MDs and release zone;
- overpressure (15 Pascal) in the conditioning zone for linen, storage zone and in the airlock;
- atmospheric pressure in the reception and sorting zone for linen, cleaning zone, changing rooms and in the adjacent zones.

If linen is sterilised, it must be packed in a different room from where MDs are packed to avoid particles.

Air from the cleaning and disinfection zone may be recycled provided it is treated. Should that not be the case, then it must be diverted outside. The air must be changed at least 6 times an hour.

The requirements listed above are only meaningful if the hygiene procedures are strictly observed (cleaning, hand hygiene, clothing requirements, etc.).

[8] Best Practice Guidelines for Cleaning, Disinfection and Sterilization in Health Authorities - December 2011 - CANADA
[9] Class ISO 8 determines the permissible maximum concentrations (particles/m³ air) of particles that are equal to or greater than 3,520,000 for 0.5 µm; 832,000 for 1 µm and 29,300 for 5 µm.

3.2 Minimum equipment

The following equipment must be present in the CSD in sufficient numbers to process the used MDs within an acceptable time:

- automatic double-door cleaning and disinfection equipment between the cleaning and disinfection zone and the conditioning zone;
- automatic double-door sterilisers between the conditioning zone and the release zone;
- additional equipment (ultrasonic units, welding machines, etc.).

The capacity must be sufficiently large to guarantee the continuity of the processes.

3.3 Hygiene

The hygiene rules laid down by the "hospital hygiene" service (such as hand hygiene, personal protective equipment, clothing, access to the premises, etc.) must be observed by CSD staff, technical staff, maintenance staff and visitors.
The basic clothing of staff may be the same for the different zones as long as it is adapted to the activities.

In the cleaning and disinfection zones, personal protective equipment is used when handling MDs. Staff must protect themselves against any form of contamination or accidental injury while handling contaminated material. The necessary resources are available in this regard: gloves with long cuffs, protective aprons, goggles (or protective screens), appropriate footwear, etc. When exiting this area, this protective equipment is thrown away or disinfected and hands must be washed in a specially designated sink (Swissmedic, 2016).

When accessing the conditioning and release zones, hands must be washed and disinfected with an alcohol-based solution.

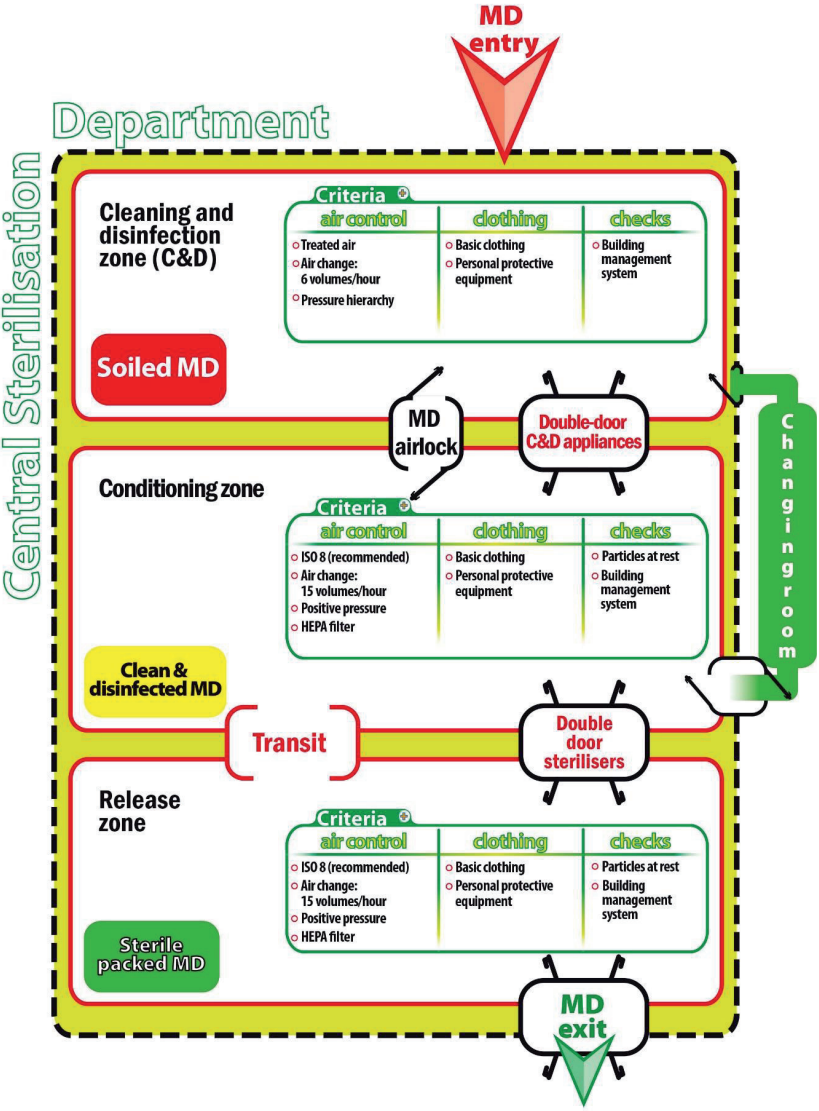
The minimum requirements for conditioning and release zones are basic clothing, the wearing of a cap and the availability of alcohol-based solutions for regular disinfection of hands (Kwok et al., 2015).

One expert does not agree on this point, and wishes to impose the wearing of gloves in the packing zone for packing MDs. His position is outlined in annex 2.

According to the HGR 9344 recommendations[10], the wearing of gloves is only appropriate in situations where the MD is a carrier of contagious micro-organisms that can be transmitted through contact or if the MD is soiled with bodily fluids.
The use of gloves is a waste of resources, without helping to reduce the risk of cross-contamination. It can also lead to a failure to comply with the alternative options for hand hygiene.
The recommendations for hand disinfection apply when handling MDs in the CSD (CSS 9344, 2017).
Eating, drinking and smoking are expressly forbidden in the premises reserved for handling MDs.

[10] Recommendations relating to hand hygiene while providing care - 2017 revision

Scheme 2. Summary of the requirements for air quality, checks and clothing on the premises of the CSD.



3.4 Premises

The premises are maintained daily in accordance with a procedure validated by the Committee for Hospital Hygiene.

3.5 Requirements for instrument mesh

Mesh is used to transport the MDs safely and ergonomically, from cleaning to use.
Two models are used, depending on the type of packing for sterilisation:

- for packing with trays: perforated or fine-mesh tray and sides;
- for the baskets: net with raised perforated tray and sides.

The mesh must not under any circumstances impede the cleaning and sterilisation process.
Upright or hanging mesh may not have any protruding or sharp edges or projections.

Material:
Stainless steel is recommended. Plastic is not recommended, because of its limited life, and given its sensitivity to cleaning products and high temperatures (degradation and fragility of plastic).

Dimensions and weight:
The mesh tray has a DIN[11] or ISO size or a derivative thereof.
The **maximum** permissible weight for a set of MDs is 10 kg in accordance with standard 868-8.
For ergonomic reasons, the SHC recommends allowing a maximum weight of 8.5 kg for mesh trays with contents (DSMH, 2010).

Loading:
Each mesh tray may only contain 1 layer of instruments/implants.
In certain cases it is possible to hang 1 or 2 mesh baskets above each other, provided they can be moved in one go.
The total height of the instrument trays must not impede the mechanical operation of the spray arms.
The MDs must be placed in the mesh baskets such that they are accessible to water and chemical products and to prevent blind spots in the rinsing process. The machine must not be overloaded.

Fasteners:
MDs are only fastened if necessary (general overview, small, fragile, sharp, etc.).
MD fastenings are designed such that cleaning and disinfection are not jeopardised.

There must be minimal contact between the MD and the fastening material.
Examples of fastenings by:

- fixing points;
- radial fixing or a comparable system;
- separation with metal bands.

[11] Deutsches Institut für Normung

Fasteners with a silicone mat must not affect the cleaning and disinfection process.

Extra attention must be paid to MDs made of titanium and IMH due to corrosion resulting from galvanisation on contact with stainless steel.

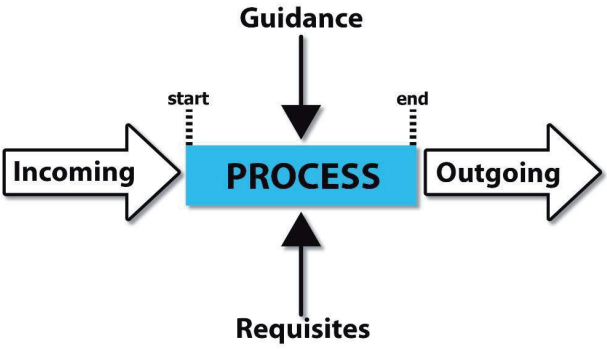
4 Process control

4.1 Introduction

The following definitions apply to the paragraph below:

- customer: service benefiting from the activity of the CSD (operating theatre, care unit, etc.);
- process: any activity that converts incoming elements into outgoing elements (product). The outgoing elements of a process often form the incoming elements of a subsequent process.

Figure 3. Process



Because end product control is not possible, the sterilisation processes must be validated before being applied. The validated processes must be routinely checked and the equipment maintained appropriately. The continuous evaluation of processes and their consistent implementation are necessary to ensure the quality of the end product.

Effective control of the bioburden is essential and can only be achieved through cleaning and disinfection methods that have previously been validated. This can also be done by managing environmental factors (premises, ambient air, staff, etc.). These are not only important when preparing the MD, but also when storing both end products and consumables, packaging material in particular.

4.2 Validation

Validation consists of verifying, recording and interpreting the test results to ensure that the process is running within the predefined limits and that a product is delivered that satisfies requirements (disinfected, sterile, etc.).

In summary, this validation of equipment in the CSD consists of: installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).
The manufacturer must have established a test protocol for each qualification in accordance with existing standards.

The following elements are usually found to reoccur for the various steps:

- IQ: properly connected in accordance with the manufacturer's specifications;
- OQ: functions correctly;
- PQ: target quality level is achieved.

It is recommended that the PQ be carried out by an external partner; the IQ and OQ can be carried out by the manufacturer/supplier.

These three qualifications are carried out before the equipment is commissioned for use. Routine tests must then be carried out to ensure consistent quality. The routine tests chosen must be the same as those used during the PQ.
The nature and frequency of these tests must be defined in a procedure that was validated and justified in accordance with the applicable standards.
The routine tests include the annual requalification and periodic tests.

The equipment must also be maintained in accordance with a preventive maintenance plan as specified by the manufacturer.

4.3 Quality management system

4.3.1 Introduction

Ideally the CSD is certified to the EN ISO 13485 standard. The CSD is at least included in the quality policy and quality assurance process of the hospital. Within the framework of his or her duties, the hospital pharmacist is responsible for establishing and maintaining a quality system specifically for the CSD. The management must appoint a member of the CSD executive who will be responsible for introducing the quality assurance process, report to the management on the quality management system and ensure that the regulatory requirements and the requirements of customers are taken into account.

Below is a brief overview of the various elements that comprise the quality management system, as described in the EN ISO 13485 standard for MDs. The terms "organisms" and "suppliers" from the standard were replaced by "institution" and "CSD" to improve understanding.

4.3.2 General

A quality system consists of the entry, documenting, recording of data and the implementation of a process such that a product is guaranteed to be designed and manufactured according to a certain level of requirement. The documentation system must contain all elements of production and must be monitored (approval, revision, version, etc.).

All the elements mentioned below must be documented. All records must be kept (for at least 16 years [12]) to provide evidence of conformity with the requirements and of the effective functioning of the quality management system.

The documentation system provides an overview of the structure of all documentation used, defines the scope, refers to the procedures and describes the links between the processes of the quality management system.

4.3.3 Responsibility

The management undertakes to support the development of the quality management system in the institution. The management shall establish a quality policy, free up resources, determine the quality objectives to be met in accordance with current legislation, appoint managers to represent it within the services and ensure good communication.

The management assessment is carried out annually. This allows management to assess the quality assurance process by consulting various elements of the quality management system (audit report, customer satisfaction, explanation of adverse events, etc.).

4.3.4 Resource management

The CSD must possess the necessary personnel and infrastructural resources (premises, equipment, logistics, consumables, work environment) to implement quality management and meet regulatory requirements and the requirements of the customer.

4.3.5 Process management

The quality objectives and product requirements must be the subject of documented processes and records showing that the MD complies accordingly.
Good communication shall be established with the customer, and his or her requirements regarding the MD shall be defined.

By analogy with standard EN ISO 13485, which describes the steps for designing and purchasing the MD, the approach to MDs in the CSD must be included in documented and validated procedures (type of MD, dismantling, cleaning method, sterilisation method, regulations, and consumables).

[12] 16 years = 15 years under criminal law after the production date + one year's margin

The production process must take place in a closed system. The vital steps of this process must be checked and validated using measuring instruments. This may involve validating the equipment, processes, infrastructures or staff training. The measuring instruments shall be identified, documented and where necessary calibrated.

All records associated with production must be included in a traceability system. The information on the condition of the MD, the handling, processing and delivery must be identified in the traceability system.

4.3.6 Measures, analysis and improvement

The CSD shall set up control systems to ensure that the MD retain constant quality over time through regular internal audits and process controls.

Conformity with MD requirements shall be assessed in accordance with the procedures described. Non-compliant MDs must be detected and if necessary removed.

The control data are documented and analysed to improve processes through corrective and prevention action.

The CSD shall ensure that the requirements of the customer are being met by regularly checking customer satisfaction.

4.4 Risk analysis

Besides identifying the causes and effects of a possible failure of a process or means of production, the objective of a risk analysis is also to identify actions that could eliminate that possible failure (or at least limit its impact and/or frequency).

This risk analysis therefore consists of considering potential failure-causing dysfunctions before they occur; this mainly makes it a predictive method.
The development process of the risk analysis must be documented.

In the case of sterilisation, the basic requirements are determined (e.g.: water, electricity, network, etc.).
Each of these requirements is then analysed as part of the overall operation of the sterilisation process in order to identify the main risks. Proposals for improvements are formulated and included in the procedures.

After that a risk analysis of the specific processes is also carried out (e.g. risk of a non-sterile MD after an undetected fault in the cleaning system).

One of the methods for assessing possible faults is the FMECA method (**F**ailure **M**ode, **E**ffects and **C**riticality **A**nalysis (annex 3).

VI CLEANING AND DISINFECTION

1 Introduction

Cleaning and disinfection of reusable MDs are not only very important steps preceding the sterilisation process, but also ensure that the MD can safely be handled by staff in subsequent zones.

An MD that was used on a patient must always be regarded as potentially contaminated and handled as such. The nature of the potential contamination and the sometimes high level of soiling make it necessary to limit prior manual operations as much as possible. Correctly maintained machinery in the cleaning and disinfection zones and validated processes (EN ISO 15883) will ensure a good cleaning result and disinfection with proper loading.

Mechanical cleaning is the standard because it is reproducible, verifiable and documentable. Manual cleaning and disinfection are reserved for exceptions.

Each operation while cleaning and disinfecting used MDs requires adapted protective measures for the worker.

2 Managing soiled MDs

In the operating theatre, care is taken to ensure that on leaving, an instrument set with MDs is complete, sorted, free from sharp objects, does not contain any waste or single-use MDs, etc.

The used MD is preferably transported to the CSD dry and as quickly as possible in a separate circuit, or if this is not possible then in a closed system.
Corrosive substances must be removed as quickly as possible.

Cleaning and disinfection are carried out in the CSD.

Storing the MDs in decontamination fluid during transport to the CSD is laborious and not justified from an ergonomic perspective.

3 Methods of cleaning and disinfection

3.1 Pretreatment

If necessary, the MD shall be opened or dismantled to ensure maximum contact with the detergents and disinfectants.

The ultrasonic unit is a useful tool for loosening contamination in places that are hard to reach for water jets and brushes. Ultrasonic treatments are also recommended for mechanically fragile instruments (microsurgery, dental instruments). The MD must be compatible with ultrasonic treatment (in accordance with the manufacturers' instructions).

The following points must be taken into account for optimal ultrasonic action:

- The ultrasonic bath must be filled in accordance with the manufacturer's instructions.
- A suitable detergent and/or disinfectant (CE class IIb in accordance with European Directive 93/42/EEC) must be added to the water.
- The concentration, temperature and time of the ultrasonic treatment must be aligned in accordance with the manufacturer's instructions.
- Filling the bath with hot water (40°C and 45°C) is recommended. The water quality (minimum softened water) is very important for the quality of the treatment and the life of the MD. Temperatures above 50°C can lead to blood incrustation due to protein denaturation.
- The water in the ultrasonic bath should be replaced in good time to avoid influencing its action, at least once a day.

The frequency varies between 35 and 80 kHz depending on the MD to be cleaned and ultrasound-treated.

With a low frequency, cavitations are greater and the effect more powerful. Conversely, a higher frequency reduces the size of the cavitations and thus the risk of degradation of fragile MDs (AFS, 2014).

The duration of treatment with ultrasonic waves varies between 3 and 5 minutes depending on the strength of the electrodes, the number of electrodes and the frequency of the waves. The greater the frequency, the longer the duration.

It is advisable to test the proper functioning of the equipment at least once a week with commercially available process challenge devices (PCD).

3.2 Mechanical cleaning and disinfection

Mechanical treatment is preferred in a standardised cleaning and disinfection process. Good cleaning and disinfection is very important, both for the life of the MD and for a successful sterilisation process. Based on international standards (EN ISO 15883) and national guidelines, only validated mechanical cleaning and disinfection processes may be used. The general requirements for cleaning and disinfection equipment are described in part 1 of EN ISO 15883.

The quality of the cleaning process and of the disinfection is determined by the following parameters: mechanical effect of the cleaning, use of appropriate detergents, temperature and exposure time and water quality.

The following detergents are recommended for the cleaning process in combination with **thermal disinfection**:

- alkaline detergent,
- enzymatic detergent.

Optional products for use after cleaning:

- neutraliser,
- drying agent (attention: some plastics can be damaged by these agents).

These must be CE-marked and classified as MDs in accordance with European Directive 93/42/EEC (RD of March 1999).

To obtain a correct cleaning result, the cleaning and disinfection machines must be loaded such that each instrument undergoes all process parameters as far as possible. This can be achieved by specially developed washing programs, the necessary connections or a specific loading trolley.

Cleaning and disinfection cycle

A complete cycle includes at least the following phases: pre-rinsing, cleaning, rinsing, disinfecting and drying.

Thermal disinfection takes place with reversed osmosis water.

Like the F_0 cycle, used to determine the sterilisation value (annex 4), the EN 15883 standard includes the A_0 cycle for thermal disinfection.
"A" is defined as the corresponding time in seconds at a temperature of 80°C to achieve a certain disinfectant effect.
If the temperature is 80°C and the Z-value is equal to 10, the term "A_0" is used.

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

Z = 10°C (thermal destruction factor)
T = set temperature
Δt = duration of disinfection (seconds)

Table 1 shows a number of temperatures with the corresponding times that can be used to achieve reliable thermal disinfection.

Table 1: Guide values for temperature and exposure time for thermal disinfection

Temperature	A_0 = 600		A_0 = 3,000	
In C°	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

An A_0 value of at least 600 is required for an MD that will undergo sterilisation after disinfection. An A_0 value of at least 3,000 is required for an MD that will not undergo sterilisation after disinfection (EN 15883-2).

A cycle consisting of cleaning and prior to cleaning **chemical disinfection** is reserved for the mechanical treatment of heat-sensitive MDs (e.g. Doppler probe, flexible uteroscope, etc.).

The sequence of steps in the cycle is the same as for the cleaning cycle with thermal disinfection.
The disinfection phase is carried out by mixing demineralised or osmosis water with a validated disinfectant (in compliance with the European directive) for mechanical use.
The degree of disinfection depends on the spectrum of the product, the temperature, the concentration and the contact time. Rinsing takes place with osmosis water.

3.3 Manual cleaning and disinfection

Because manual cleaning and disinfection is not reproducible, verifiable or documentable, it is reserved for exceptional situations.

Manual cleaning may only be applied to MDs that cannot be cleaned mechanically. The supplier must provide a validated cleaning and disinfection procedure for these MDs. The responsible hospital pharmacist assesses whether the MD can be reprocessed within the CSD.

The manually cleaned MD must then undergo chemical disinfection.

It is important that predetermined and validated contact times are observed.

- The chemical disinfectant must satisfy European standards (ISO, CE) and its effectiveness must be demonstrated in relation to pathogens that may be found in hospitals.
- The product used must be compatible with the MD in accordance with the recommendations of the manufacturer.

After chemical disinfection, the MD is rinsed and dried.

A specially developed drying cabinet should preferably be used for drying. Alternatives include medical compressed air or lint-free disposable cloths.

All cleaning aids, such as cloths, brushes, etc., are preferably single-use, otherwise these must be cleaned and disinfected at least once a day.

3.4 Validation

A validation plan is required for all automated cleaning and disinfection processes. The requirements from standard EN ISO 15883 must also be satisfied with IQ, OQ, PQ and routine tests. These mandatory periodic checks offer a guarantee of quality and conformity (see Table 2).

Table 2. Performance and frequency of tests in connection with the validation of cleaning and disinfection

Validation plan			
At installation			
Subject	**Description**	**Frequency**	**Operator:**
IQ	Determines whether the machine is operational	1	Manufacturer
OQ	Determines whether the machine is functioning correctly	1	Manufacturer
PQ	Determines whether the machine meets the performance objectives	1	User/qualified external company
In routine			
Subject	**Description**	**Frequency**	**Operator:**
Water quality	Analysis of the last rinsing water	1 to 4x/year	User/qualified external firm
Product dosing	Dosing of all detergents and disinfectants	1 to 4x/year	User/qualified external company
Effective cleaning	Assessment of the cleaning result using soiling tests	1 to 4x/year	User/qualified external company
Thermometry	Assessment of the thermal disinfection	1 to 4x/year	User/qualified external firm
Doors	It is not possible to open the door during a cycle	1 to 4x/year	User/qualified external firm

The frequency of the routine tests depends on the reliability of the installation and the risk analysis.

For periodic inspections of the cleaning results, all kinds of aids can be used, such as a swab test, a soiling test or microbiological testing. All these resources quickly and simply indicate whether the required quality is still being maintained.

Besides this validation plan, permanent checks of the results are essential.
A visual inspection immediately after cleaning and disinfection makes it possible to check whether the MD is dry, clean and free of chemicals.

The process parameters of each mechanical cleaning and disinfection cycle are recorded and checked automatically.

The daily inspection of the machines (filters, washing arms) must be able to guarantee their proper functioning; these inspections are described in procedures.

VII CONDITIONING

1 Inspection and maintenance of MDs

Each MD is checked before being packed.
In any event, the recommendations of the MD manufacturer must be strictly followed.

1. MDs must be visually clean.

Possible aids include a lamp with a magnifying lens, a magnifying camera, a microscope, etc. If there is any doubt about the cleanliness of the MD, it must cleaned again.

2. MDs must be maintained.

MDs with hinges must be lubricated if necessary, with fixed optics the distal and proximal lenses are cleaned with a soft cloth soaked in alcohol.

The maintenance products intended for MDs must satisfy the following requirements. They must:

- be biocompatible in accordance with the prevailing European Pharmacopoeia;
- be suitable for sterilisation with the chosen sterilisation method and be permeable to the sterilising agent;
- in accordance with the instructions of the MD manufacturer.

NB. MDs must not be treated with maintenance products containing silicone oil. This may make it more difficult for the MDs to function properly, and may have an adverse effect on the operation of the steam sterilisation.

The maintenance measures are carried out before the functional inspection. The friction of metal on metal is thus avoided, and consequently corrosion through contact. The proper functioning of MDs is thus guaranteed.

3. The integrity of MDs is checked.

This includes:

- the intactness of the coating of the instruments,
- the stiffness of the hinged part,
- checking for the presence of corrosion, scratches, cracks, etc.

4. The functionality of MDs must be checked

Among other things, the check includes:

- the cutting power of scissors,
- the gripping and securing capacity of needle holders, tweezers, clamps, etc.,
- the integrity of the optics,
- the functioning of the cables.

Dismountable MDs must be re-assembled for the functional inspection.

2 Replacing MDs

All non-compliant instruments must be repaired, removed or replaced.

New MDs or those repaired must at least undergo a complete cleaning and disinfection cycle.

3 Composition of sets

Several rules can be followed when putting sets together:

- course of procedure,
- user requirements,
- similar MDs are placed together,
- heavy MDs are placed below lighter or more fragile ones,
- sharp and fragile MDs are protected,
- the entire MD (e.g. lumens) must be accessible to the sterilising agent.

Only as many MDs as necessary for a single treatment or care procedure may be present in the same package.

The **maximum** permissible weight for a set of MDs is 10 kg in accordance with standard 868-8.
For ergonomic reasons, the SHC recommends allowing a maximum weight of 8.5 kg for mesh trays with contents (DSMH, 2010).

4 Packaging

The MD must be packed such that sterility is guaranteed until the time of use and an aseptic presentation is possible.

The packaging is the subject of a validation, from the design of the packaging to use.

The choice of packaging material and the packing method are always dependent on the sterilisation method to be used, the nature of the MD to be sterilised and the conditions under which these are transported, stored and used.

4.1 General

4.1.1 Standards

The packaging must satisfy the EN ISO standards: EN 868-1 to 8 and 11607-1 and -2.

ISO standard 11607 describes the requirements of the material, the packaging systems, including the qualification of the design of the packaging system and the assessment of the design. The second part addresses the validation of the packing process.

The packaging system according to the definition in standard 11607 consists of a system of a **sterile barrier** and **protective packaging.** The protective packaging is adapted to the storage and transport conditions. The packaging system must allow the aseptic presentation of sterile MDs.

The organisation for standardisation has published a guiding document (ISO TS[13] 16775) explaining the application of ISO 11607.

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

4.1.2 Application

The choice of sterile packaging system is the subject of a validation. The assessment criteria for choice and implementation must be documented.

The packaging must be permeable to air and the sterilising agent.
The packaging must be able to undergo the chosen sterilisation process without its properties being fundamentally altered.

The manufacturer of the packaging must provide an expiry date, after which the packaging must no longer be used. In addition, an expiry date must be applied when sterilising the packaging system (in accordance with the production batch). This last date may not be after the expiry date of the packaging.
The packaging system must have passage indicators enabling the user to check whether the material has undergone a sterilisation process.
These passage indicators are not a guarantee of the MD's sterility.

Nothing is added to the outside of the packaging that inhibits the action of the sterilising agent and jeopardises sterility (correct dimensioning and positioning of the label, nothing written or stuck to the packaging, etc.).

No contaminant (paper, ink, compress, etc.) whatsoever may be placed in the same set together with MDs. A physico-chemical indicator is not a contaminant.

The integrity of the packaging system must remain guaranteed from sterilisation to the use of the MD.

The packaging system and sterilisation process must be revalidated when the packaging or packaging method is changed if this affects the initial validation (EN/TS 16775).

4.2 Packaging materials and methods

4.2.1 General

The packaging system consists of a **sterile barrier system** and **protective packaging** and may vary.

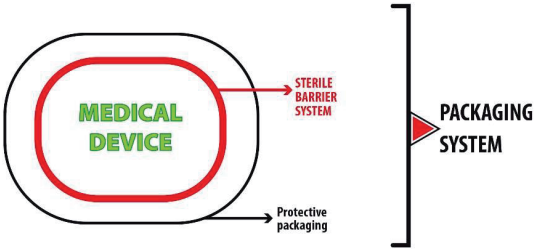
The sterile barrier system prevents the penetration of micro-organisms in the specified conditions. This allows aseptic opening.

[13] Document ISO TS 16775 provides guidelines with a view to the assessment, selection and use of packaging materials: preformed sterile barrier system, sterile barrier systems and packaging system. It also offers recommendations for the validation requirements relating to the design and assembly processes.

The protective packaging is intended to prevent damage to the sterile barrier system and its contents from composition to the time of use.

If transport compromises the packaging system, extra transport packaging should be used.

Figure 4. Packaging system



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 trolleys, closed trolleys, distance between sterilisation and storage location, etc.) and the protection of staff. Particular attention is paid to the weight and shape of the sterile set.

4.2.2 Packaging using sheets

The sheets can be made of paper or nonwovenwrap and must satisfy the requirements of microbiological barriers. The sheets have a batch number.

Folding techniques

The validated folding techniques are included in recommendation ISO TS 16775.
The ends of the sheet must overlap each other properly. However, the sheet must not be too large to avoid too large a number of folds, which could slow the penetration of the sterilising agent and the drying process and obstruct the aseptic offering of the item. The most common folding techniques are the envelope method, packet method (Chinese fold or parallel method) or rolling method (Pasteur) (see annex 5).
The packaging must be closed with self-adhesive tape and must have a passage indicator (in conformance with EN 867-1 class A).
The tape must be of such quality and be properly applied to the packaging so that it remains closed both during and after the sterilisation process.

4.2.3 Packaging using pouches

The pouches or rolls can be constructed from a combination of paper laminate or polypropylene laminate or other polymers that are compatible with the sterilisation method. These have a batch number.

The preferred method is to use laminate pouches. Such pouches are also known as peel-off *(or peel-apart)* pouches. These make the contents visible and allow 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.

When using double packaging, the dimensions of the pouches must be chosen such that the inner pouch can move freely in the outer bag to ensure good penetration of the sterilising agent between the layers and avoid the layers possibly sticking together. Folding the innermost packaging must be avoided.

The pouch is closed by means of a validated welding device, which must be tested daily with a suitable test (EN 11607). Each weld must be checked prior to sterilisation.

4.2.4 Containers

Containers must comply with and be validated in accordance with the following standards: EN 868-8, EN 16775, EN ISO 11607-1 and -2.

After each use, the containers must be cleaned, disinfected and checked for integrity. The container forms part of a maintenance plan 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. An adapted sealing system is used.

4.2.5 Textile

Woven textiles are **not permitted** for setting up a sterile packaging system.

5 Labelling

To ensure optimum traceability, the label may include the following elements:

- the production date;
- the name of the institution;
- the sterilisation method;
- the text "sterile if packaging is undamaged";
- the batch number;
- the unique identification number of the set, which allows the composition of the set to be traced;
- the expiry date;
- the name of the customer, the name of the set;
- the storage place;
- the barcode, data matrix, etc.

VIII STERILISATION PROCESSES

MDs can be sterilised by various processes, depending on the thermal resistance of the MDs being sterilised. A distinction is made between high-temperature and low-temperature sterilisation.

Various sterilisation methods are recognised:

- sterilisation by physical destruction processes (heating or radiation);
- sterilisation by chemical processes (gas);
- sterilisation by removal processes (filtration).

The radiation, filtration or sterilisation of liquids is not discussed in this document.

Hot-air sterilisation and formaldehyde/steam sterilisation are no longer recommended by the SHC.

As things stand, only the sterilisation processes listed below are used to sterilise MDs in hospitals:

- sterilisation with saturated steam;
- sterilisation with hydrogen peroxide (H_2O_2);
- sterilisation with ethylene oxide (EO). This method can only be allowed if the environmental regulations and NBN EN1422 are complied with and the EO concentration remains within the limits (danger of explosion). Given the limitations and risks associated with this sterilisation method, the SHC does not recommend it in hospitals.

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

1 Sterilisation using vacuum distillation and saturated steam

1.1 Introduction

Sterilisation by means of damp heat with pressurised saturated steam is recommended because this process is the most reliable and the easiest 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 is exposed to pressurised saturated steam at a certain temperature and for a certain time.
The micro-organisms are killed by the condensation of the saturated steam.

Steam sterilisation is based on a thermodynamic balance between pressure and temperature that must be maintained during the different phases of the sterilisation processes and which is only achieved if the steam is saturated (see table 3).

Table 3: Regnault's table

Actual pressure	Absolute pressure	Temperature	Actual 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

Note: 1 bar equates to 10^5 pascal, or 100 kPa.
Absolute pressure = Actual pressure + atmospheric pressure

1.3 Process sequence

1.3.1 Packaging method

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

1.3.2 Loading the steriliser

Loading is an essential phase in the sterilisation cycle. The sterilising medium must be able to reach all the surfaces to be sterilised. The instructions provided by the manufacturer of the steriliser must be followed during loading. The loading procedure forms part of the validation of the sterilisation cycle.

To avoid poor penetration of the steam into the load, an inadequate transfer of calories or steam condensation on the MD that is difficult to control, it is strongly recommended not to exceed the limits of 8.5 kg[14] (EN 285, 2016).
Due to condensation concerns, it is recommended that heavy MDs, laminate, and plastics be placed at the bottom.
Contact with the chamber walls must always be avoided.
There must be sufficient space between packaging systems (do not stack).
Textile packs are sterilised in a specific, validated sterilisation cycle. This is because the drying phase for textiles takes longer than the standard cycle and includes several pressure changes.

1.3.3 Cycle sequence

(a) Preconditioning: removal of air and preheating

Adequate air removal is essential for a good sterilisation cycle. If the air has not been completely removed, the thermodynamic balance between temperature and saturated steam pressure is disrupted, and sterility cannot be guaranteed.

[14] Contents without the packaging system

The air is removed from the room by successive vacuums (fractionated vacuum distillation), each followed by injections of saturated steam. A vacuum of at least 70 mbar (ref. EN 285) must be reached.

This preconditioning ensures that the MDs are heated and the predetermined guide values for temperature and pressure are reached in the chamber.

(b) Sterilisation plateau

According to standard EN 285, as soon as this balance is reached, the actual sterilisation phase begins, for 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.

(c) Drying

At the end of the plateau phase, the condensate on the MD must be removed by a combination of vacuum, residual heat and air intake (sterile filtered air).

1.3.4 Unloading and load release

Parametric release is the declaration of conformity of product sterilisation based on the measurement and evaluation of physical parameters (time, pressure, temperature). The parametric release of the loads is only permitted if the steriliser has been validated.
In addition to parametric release, permanent checks must be carried out (see point 1.5.2.).
The load can only be released if all parameters are satisfied.
If one of these parameters is not satisfied, the load must be re-packed and sterilised again.

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

1.4 Malfunctions

The causes of non-conformity in steam cycles are:

- the presence of air and non-condensable gases in the load as a result of inadequate removal of air 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 plateau phase.

1.5 Testing

1.5.1 Daily check

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

The following can be used to carry out this test:

- The ready-to-use test packs: class 2 indicators (see annex 6). The Bowie & Dick test packs must meet the specifications described in standards EN 285, EN 17665 (554), EN 11140-3 and EN 867-4.
- Other alternatives (such as electronic tests): the SHC recommends that their use be permitted if the manufacturer is able to produce evidence of performance with the methods described in standard EN 11140-4.

In the event of a non-compliant Bowie & Dick test, the cause of the malfunction is determined. Production can only start after a compliant Bowie & Dick test.

1.5.2 Permanent check

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

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

If one of the results of these checks is non-compliant, the products are regarded as not sterile.

1.5.2.1. Checking cycle parameters

Each steriliser is equipped with recording equipment for temperature and pressure as a function of the time needed to be able to check the parameters of the cycle. The following must be checked on the graph: the level and the number of vacuums, the sterilisation plateau (temperature, pressure, time) and the drying phase. The course of the graph must be identical to those 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 3). During the plateau phase of sterilisation, the steam must have a temperature that corresponds to its theoretical steam pressure.
The sterilisation conditions determined must be based on a recognised time/temperature ratio.

1.5.2.2. Check by means of physico-chemical indicators

Class 1 indicators are used for this type of check.

These passage indicators are applied to tapes or packaging material and only react to "temperature", and then only approximately; they do not provide any indication of time. The change of colour indicates that the MD has undergone a sterilisation cycle. This does not guarantee the effectiveness of the process, and in no way proves that all micro-organisms present have been destroyed (annex 6).

1.5.2.3. Dryness check

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

1.5.2.4. Checking packaging integrity

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

1.5.3 Weekly check

The weekly check consists of a physical check of the vacuum tightness.
Once a vacuum is reached that is less than or equal to 70 mbar, this test enables a check to be carried out of whether this vacuum is maintained at the same pressure reading.

A maximum increase of 13 mbar/10 minutes is permitted. This test checks whether there is a leak in the door seal, whether the chamber is free of leaks, etc. (Standard EN 285).

NB. Testing using biological indicators
Based on current knowledge and practices, the SHC is of the opinion that it is no longer appropriate to carry out microbiological tests. The F_0 of a biological test is based on 15 min. at 121°C, while that of the cycles used is F_0 60 for a cycle of 3 min. at 134°C and F_0 360 for a cycle of 18 min. at 134°C (annex 4).

1.5.4 Validation

(a) Reference framework

In response to the application of the RD of 18 March 1999, steam sterilisers must bear the CE marking along with the number of the notified body.
The following standards apply:

- EN 285 (revised in 2016) determines the requirements and tests for large steam sterilisers.
- EN 13060 determines the requirements that apply to steam sterilisers where the capacity of the steriliser chamber is less than 60 litres (small sterilisers).
- EN ISO 17665 (2006) specifies the requirements for the development, validation and routine checking of an MD sterilisation process.

A validation plan is required for all steam sterilisers. The requirements from standards EN ISO 17665 and EN ISO 285 must also be satisfied with IQ, OQ, PQ and routine tests. These mandatory periodic checks offer good practices a guarantee of quality and conformity.

(b) Commissioning the steriliser (IQ)

The IQ of the steriliser on commissioning is carried out in an empty chamber and provides certainty that the appliance delivered is installed and functions according to the specifications and technical parameters provided by the manufacturer. This step is performed by a technician from the supplier.
The specifications detail the equipment used and its limitations when used, the installation procedure, the predetermined programs, the calibration, the maintenance, etc. All measuring instruments and recording equipment for the key parameters are calibrated to obtain accurate, reproducible data. The steriliser is also supplied with specifications on the space and environment in which the steriliser may/must be placed. These conditions must ensure that the sterilisation process is effective, reproducible and uniform at all points of the chamber (WIV, 2011).

(c) Validation of function (OQ)

OQ takes place after the appliance has been installed by the supplier's technician. The aim is to check whether the steriliser delivers the expected sterility of the MD in accordance with the specifications.

The specifications concerning the validation of the sterilisers must provide an accurate description of the requested tests:

1. temperature profile for an empty cycle
2. Bowie & Dick cycle
3. leak test
4. qualification of one type of load, the validation test must take place under the appliance's normal anticipated conditions of use
5. check of each type of sterilisation cycle (position of the probes, monitoring of parameters, choice and position of the physico-chemical or bacteriological indicators, etc.)
6. dryness check. The final dryness of the load is established by standard EN 285: "*the increase in relative humidity measured by weighing the load before and after sterilisation and reduced to the weight of the load prior to sterilisation*". For a metal load, the weight increase must be less than 0.2 %, for a load of linen less than 1.1 %

Reproducibility is ensured by repeating the checked cycles three times.

(d) Validation of performance (PQ)

The purpose of PQ is to demonstrate that the sterilisation process is able to reach a predetermined sterility assurance level (SAL) for the load concerned, and this on a repeated basis (ISO 17665).

PQ must demonstrate that the load was actually exposed to the conditions for sterilisation determined during OQ.

The efficiency of sterilisation with saturated steam is partly determined by the load, since this influences the temperature and contact time. The sterilisation therefore has to be validated using a load that is representative of the loads routinely placed in the steriliser. The curve of the temperature in the steriliser chamber can be determined with measuring probes spread around the chamber and the load. The saturated steam penetration must be checked by measuring the temperature in the loads or in "reference packs" placed in the coldest zones of the steriliser chamber. These coldest zones were determined by the manufacturer and on the basis of earlier steps in the validation of the appliance.

PQ must involve at least three successive cycles, each of which must demonstrate that the procedure satisfies the requirements for sterilisation (WIV, 2011).
The documentation of all initial tests must be kept for as long as the steriliser is in use.

This validation must be carried out by a qualified third party (not the supplier/manufacturer).

(e) Routine check

A maintenance plan is required for the appliance to maintain proper functioning.
Periodic routine tests carried out by the user safeguard the conditions measured during validation.

Table 4 shows the minimum tests to be carried out, who must/can carry these out and the frequency to EN 17665 and EN 285.

Table 4. Performance and frequency of tests in connection with the validation of sterilisation with saturated steam (EN-17665)

Validation plan			
At installation			
Item	**Description**	**Frequency**	**Operator**
IQ	Determines whether the machine is ready for use	1	Manufacturer
OQ	Determines whether the appliance delivers the expected sterilisation	1	Manufacturer
PQ	Determines whether the load was correctly exposed to the sterilisation process	1	Qualified user/external firm
In routine			
Item	**Description**	**Frequency**	**Operator**
Quality of the steam quality	Analysis of the water supply in accordance with the standard qualifications	1x/year	Qualified external firm
Bowie & Dick test	Evaluation of the actual air extraction and good penetration of the steam	Daily	User
Vacuum leak test	Evaluation of the tightness of the steriliser vat	1x/week	User
Thermometric test	Evaluation of sterilisation with a routine load	1x/year	Qualified user/external firm

2 Sterilisation with hydrogen peroxide (H_2O_2)

2.1 Introduction

This sterilisation process is one of the current alternatives within hospitals for low-temperature sterilisation. There is no specific standard for this process, but a general standard, ISO 14937, which defines the general requirements to develop, characterise, validate and routinely check a sterilisation process for an MD.
All data described by the standard and those arising from the development of such a process must be documented and made available to the user by the manufacturer of the steriliser.

Hydrogen peroxide sterilisation (low-temperature sterilisation) is designated in hospitals for the sterilisation of heat-sensitive MDs. There are a number of restrictions with this method: nature of the MD, lumen claim, dryness of the MD, absence of cellulose.

The manufacturer of the MD, in consultation with the manufacturer of the steriliser, offers the user the guarantee that an MD can be sterilised in the conditions determined by them (ISO 16664). The manufacturer's guidelines must be strictly followed.

2.2 Principle

Under a deep vacuum and preconditioning (increase in temperature and drying) the MD is subjected to injections of H_2O_2, followed by a diffusion phase. Sterilisatie arises from the exposure to H_2O_2, which destroys the membranes/walls of viruses and bacteria by oxidation, as well as partially attacking proteins.

The lethal action of H_2O_2 must be proven for representative micro-organisms, with the kinetics of their inactivation being demonstrated. Based on the results of these tests, the manufacturer advises a reference micro-organism for biological tests.

At the end of the process no residues of H_2O_2 may remain, and its release must not present a danger to the user or the environment.

The manufacturer provides the user with documents describing the parameters that influence the process. The user must satisfy himself/herself that the parameter values remain within the limits for each cycle, thereby guaranteeing the effectiveness of the process.
These parameters include: pressure, temperature, contact time with H_2O_2, concentration of H_2O_2, volume of the chamber, surface to be sterilised, maximum load weight, type of material, etc.
The effectiveness of the process must be demonstrated by using conditions that are less lethal than those in the routine process (1/2 cycle, for example).

2.3 Process sequence

2.3.1 Packaging

The MD must be packed in a packaging system compatible with the sterilisation method using H_2O_2. This compatibility must be validated by the manufacturer of the steriliser.

2.3.2 Loading the steriliser

Loading is a key phase of the sterilisation process. The sterilising medium must be able to reach all the surfaces to be sterilised. The instructions of the steriliser manufacturer must be observed during loading.

2.3.3 Cycle sequence

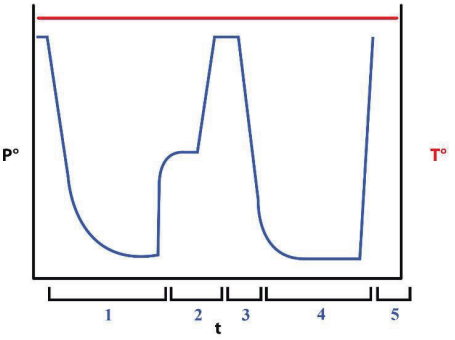
A sterilisation cycle with H_2O_2 can be illustrated in the following chart:

(1) placing under a vacuum to remove the air from the load;
(2) injecting H_2O_2 that is vaporised and is then spread over the load (diffusion);
(3) repressurising by the injection of filtered air into the chamber;
(4) placing under a forced vacuum to remove any residual product followed by a plateau phase;
(5) finally, resubjecting it to atmospheric pressure.

Phases 1-2-3 represent as such the sterilisation part of the cycle. Certain processes repeat this one or more times to guarantee sterility, in contrast to the validation cycle, where a single sterilisation phase is used.

The image below illustrates these elements in graph form.

Figure 5. Sterilisation cycle with hydrogen peroxide



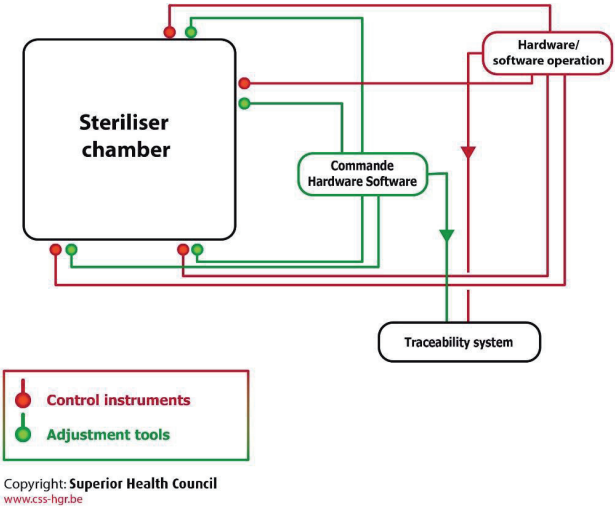
2.3.4 Unloading and load release

Biological and/or chemical indicators can be used to release the load. Where applicable, the steriliser manufacturer determines how the results obtained should be interpreted.
A parametric release can also be performed to release the load.
Definition of parametric release: *"Declaration that a product is sterile, based on records demonstrating that the process parameters were delivered within specific tolerances" ISO/TS 11139:2006, definition 2.29*.

"This is only possible if all process parameters are specified, controlled and monitored directly. The records of the process parameters must be retained." (*ISO 14937: 2009, 11.2*).

An IMS (independent monitoring system) makes it possible to satisfy the requirements of the standard. The diagram below illustrates how such a system can be set up:

Figure 6. Independent monitoring system



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

In addition to parametric release, permanent checks must be carried out (see point 2.5.2.).

2.4 Malfunctions

Several parameters can affect the result. Potential malfunctions:

- residual moisture that impedes the start or end of the cycle;
- absorption capacity of the MD;
- poor distribution of H_2O_2;
- the load is too great;
- residue left behind on the load at the end of the cycle.

2.5 Testing

The operation of the steriliser and the technical equipment must be clearly described in the documentation provided by the manufacturer for the user. Software to monitor the parameters that influence the process must be provided and developed in accordance with a quality management system. The appliance must be designed so that no defect whatsoever can lead to the misrecording of the process parameters and an incorrect interpretation of the results.
"This can occur through the use of independent control and monitoring systems or through verification between control and monitoring that identifies all abnormalities and a defect" (ISO 14937: 2009, 6.3.4).
In particular, this allows parametric release.

The continued effectiveness of the process must be ensured by routine checks, which may involve the periodic use of biological and/or chemical indicators or a PCD. The instruments for measuring the parameters that influence the process must be regularly calibrated.
The steriliser is periodically maintained according to a fixed maintenance plan as provided by the manufacturer.

The sterilisation process can be checked by:

- **Biological indicators:** (to ISO 11138-1). The micro-organism determined as a reference in relation to the process must be used to build these indicators.

- **Chemical indicators:** (to ISO 11140-1).

- **PCD**: It must mimic the properties of a load of MDs that is the most difficult to sterilise, due to the impact on the parameters that influence the process (weight, area, materials, etc.). Chemical and/or biological indicators can be placed in a PCD to measure whether the state of sterilisation has been achieved.

The steriliser manufacturer determines the use of the monitoring tools.

2.5.1 Permanent check

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

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

If one of the results of these checks is non-compliant, the MDs are regarded as not sterile.

2.5.2 Other checks

Other checks depend on the type of appliance and the manufacturer's data.

2.5.3 Validation

As with any steriliser, IQ and OQ must take place. PQ then demonstrates that the steriliser is able to deliver a sterile product during routine use. Biological indicators, chemical indicators and PCDs can be used for this. The test cycles between PQ are carried out in conditions that are less lethal than during the routine process (1/2 cycle).
Three successive sterilisation cycles must be carried out.
The documentation of all initial tests must be kept for as long as the steriliser is in use.

A maintenance plan is required for the appliance to maintain proper functioning.
Periodic testing by the user makes it possible to guarantee that the conditions measured during validation have been maintained.

Table 5. Performance proposal and frequency of tests in connection with the validation of sterilisation with H_2O_2 to EN ISO14937.

Validation plan			
At installation			
Item	**Description**	**Frequency**	**Operator**
IQ	Determines whether the machine is ready for use	1	Manufacturer
OQ	Determines whether the appliance delivers the expected sterilisation	1	Manufacturer
PQ	Determines whether the load was correctly exposed to the sterilisation process	1	Qualified user/external firm
In routine			
Item	**Description**	**Frequency**	**Operator**
Defined tests	Manufacturer recommended testing	1x/year	Qualified user/external firm

3 Ethylene oxide sterilisation

The SHC does not recommend ethylene oxide sterilisation in hospitals because of the risks and limitations
If ethylene oxide is used, this must be in accordance with EN ISO 11135.

4 Other sterilisation processes

For all new sterilisation processes, unless covered by a specific standard, there is a general standard, ISO 14937, which determines the general requirements for developing, characterising, validating and checking a sterilisation process for MDs.
All data described by the standard and those arising from the development of such a process must be documented and made available to the user by the manufacturer of the steriliser.
The requirements determined in this standard are the same as those described in the chapter on sterilisation with hydrogen peroxide.
The manufacturer must therefore provide the user with all information on:

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

The appliance used must be registered in advance as a steriliser with a national or international agency and as an MD with a notified body in accordance with the Medical Device Directive (93/42/EEC)

In the event of a change in the sterilisation method, compatibility with the new method must be verified by the manufacturer of the resterilisable MD.

IX STORAGE CONDITIONS OF STERILE MDS

1 Transport

Authorised staff must be responsible for supervising the transport of the sterile MD from the CSD to the storage zones and areas of use.
The trolleys intended for the transport of sterile MDs must differ from those used to collect soiled MDs or must be cleaned and disinfected between transports, preferably mechanically.

When the transport trolleys leave the controlled zone, they must be locked and kept under supervision. In any event, even locked trolleys must be stored in a locked, secure room.

2 Storage rooms and equipment

2.1 Central rooms and storage areas for sterile MDs intended for the operating theatre

Rooms for storing MDs must, among other things, meet the following conditions:

- The temperature of the room must be between 15°C and 25°C.
- The humidity must fluctuate around 60 %.
- The MDs must not come into contact with direct sunlight (UV).
- These rooms are regarded as semi-critical zones, so a pressure gradient is required. Class ISO 8 is recommended.
- Temperature, moisture and pressure must be monitored.
- Access to these zones must be restricted to authorised persons.
- The transport packaging must be removed beforehand in an adjacent area.
- The room must be easy to clean.
- There are no open drains, water taps and pipes.
- Floors must be smooth, impervious and undamaged.
- The room is equipped such that the MDs stand clear of the floor, walls and ceilings.
- Equipment such as shelves, cabinets and means of transport 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 a rotation of MDs according to good distribution practices and the preservation of packaging integrity.

2.2 Storage in nursing wards, medical-technical departments and polyclinics

In the services, the sterile MDs are stored in locked cabinets. These cabinets are in clean locations that do not involve any increased risk of contamination.
The temperature of the room must be between 15°C and 25°C, and the humidity must fluctuate around 60%. The MDs must not come into contact with direct sunlight (UV).
The storage and distribution of MDs must allow a rotation of MDs according to good distribution practices and the preservation of packaging integrity.

3 Storage conditions

The shelf-life of sterilised MDs is determined by means of a risk analysis and depends on a number of factors, such as the packaging material, the packing method, the storage conditions, the number and nature of handling operations as well as the stability of the materials from which they are made.

The ISO 11607 standard describes the necessary steps for validating the packaging system in care institutions. The validation file contains all the information on the materials provided by the manufacturer on the one hand and, on the other, on the tests carried out by the user in his/her/its work environment. The file justifies the storage time of the MD in a sterile state and in a correct manner.

X EQUIPMENT ON LOAN

Bearing in mind that suppliers provide hospitals with MDs and that several hospitals use the MDs, it is important that organisational and maintenance procedures are established and that each user (hospital) and intermediary (commercial company) undertakes to comply with these.

With a view to clarifying everyone's obligations and rights, the network of the Medical Equipment Committee (CMM) proposes an agreement, in accordance with the provisions of the RD of 18/03/1999 relating to MDs, with which equipment on loan must comply. More specifically, this agreement must include the following elements. Some elements are the responsibility of the supplier, others of the hospital or both.

The supplier undertakes to comply with the European directives, regulations and Belgian RDs relating to MDs.
After each non-compliance with the aforementioned documents, the hospital shall report to the FAMHP using the reporting form for materiovigilance.

1 Obligations of the supplier

- The supplier shall accurately identify the equipment on loan (name and use).
- The supplier shall identify the components of the set with up-to-date photos/pictures.
- The supplier shall provide instructions in the specified language for the staff who are going to be using the equipment on loan, containing:
    - information on the appropriate processes for reuse, including cleaning, disinfecting, packing and the sterilisation method if the MD needs to be resterilised, along with any restriction on the number of times the MD can be reused;
    - the methods for assembly and disassembly, detailed and illustrated with a diagram or photo;
    - information that is in accordance with EN ISO-17664.
    - The instructions shall only include references in compliance with the standards, guidelines and processes applicable in Belgium.
    - 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 furthermore shall verify this prior to dispatch.
- The supplier is responsible for ensuring that the equipment on loan is delivered at the appointed time, intact, complete, visually clean and disinfected.
- The supplier shall deliver the equipment on loan and accessories to a location agreed with the customer.
- Delivery shall be made in specific transport packaging, different from the packaging system (see figure 4), and accompanied by all the necessary documents. This transport packaging must be closed, clean, cleanable and have comfortable, ergonomic handles. If the packaging is delivered stacked on a pallet, the handles of the top containers must not be above a height of 140 cm (ISO 11228 - 1).
  The instrument trays or baskets of the equipment on loan must at least satisfy the requirements of these recommendations (see V. Point 3.5.).

If “position diagrams” are provided at the bottom of the mesh tray, the names and references of the MD or the size of the trial prosthesis/implant must be updated.

2 Obligations of the hospital

- The on-loan equipment received is regarded as a contaminated MD, and the standard precautions apply.
- The hospital shall verify the conformity of the equipment on loan in relation to the delivery note.
- The set shall be cleaned, disinfected and sterilised in the CSD, all of which must be carried out prior to use. The same requirements apply to equipment on loan as to an MD that is the property of the hospital.
- After being used on the patient, the on-loan equipment must be cleaned and disinfected in the CSD before being returned to the supplier.
    - The hospital shall return the on-loan equipment in accordance with the delivery.

3 Obligations of both parties

- The equipment is loaned out on the express condition that it is not to be used in autopsies and/or for animal testing.
- The on-loan equipment must be delivered at least 12 working hours (opening times of the CSD) prior to use and must be returned within 24 working hours of the intervention, unless the agreement specifies otherwise.

XI SINGLE-USE MEDICAL DEVICES

1 European regulatory framework for MDs

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices are at the basis of the regulatory framework for MDs.
These directives are aimed both at guaranteeing a high level of safety and protection for human health and at the functioning of the internal market.

Directive 93/42/EEC concerning medical devices distinguishes between devices that can be reused and devices intended for single use.

In particular the following applies:

- the label of single-use MDs must specify that the device is intended for single use;
- if an MD can be reused, the manufacturer must provide information on the appropriate procedures relating to reuse, including cleaning, disinfecting, packing and, where appropriate, the sterilisation method to be used, as well as any limitation in relation to the number of times the device can be reused.

Directive 93/42/EEC was most recently amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, which, to respond to the concerns regarding patient safety, provides further clarification of the term “single-use device” and sets out new requirements for single-use MDs.

Directive 2007/47/EC provides in particular as follows:

- “single-use device” means a device intended to be used once only for a single patient;
- the manufacturer’s indication of single use must be consistent throughout the Community;
- if the device is labelled for single use, information on properties and technical factors known to the manufacturer and which may pose a risk if the device is reused must be stated in the instructions for use (EC, 2010).

2 Definitions

Single Use: *Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure* (ISO 15223-1:2012(E), 2012).

The symbol is:

Do not resterilize: *Indicates a medical device that is not to be resterilized (ISO 15223-1:2012(E), 2012).*

The symbol is: 

Resterilisation is understood as meaning the repackaging and sterilising of MDs that are no longer sterile.

Reuse is understood as meaning the use of an MD for single use that has already been in contact with a patient.

3 Responsibilities

Resterilising or reusing can be dangerous for various reasons, in particular because of risks of contamination, impairment of the physical and functional integrity of MDs and toxicity.
On the other hand, the resterilisation cost may be higher than the purchase price of some MDs.

The reuse after reprocessing of an MD intended by the manufacturer for single use (disposable) is not regulated by current Belgian legislation (FPS, 2011).

Any use of the MD that does not comply with the use assigned by the manufacturer is not covered by the RD of 18/03/1999. The manufacturer is only responsible for the quality and functioning of the MD if it is used in accordance with the use assigned by the manufacturer.

XII TRACING SYSTEM

Traceability in a CSD contributes to the effective management of the MD and the legal protection of the institution. 'Traceability' is understood as meaning: the setting up of a system that allows the MD to be monitored in all phases of treatment and use, as well as the proactive management of the desired processes. This forms an essential part of a quality system. It is strongly recommended that every care institution introduce such a system, based on standard EN 13485. The traceability of MDs shall be computerised.

A number of criteria must be taken into consideration when choosing a computerised tracking system:

- satisfaction of the user requirements,
- user-friendliness,
- security,
- architecture of the application,
- data management,
- integration with external systems (hardware and software),
- new developments,
- technical support,
- price,
- linking of the process data of the used MD to the patient.

1 User requirements

A computer application must respond to and be adapted to the needs of users. Users must submit specifications with the requirements for the tracking system. Each requirement is given a weight according to importance and priority to be able to make an affective comparison between the systems offered.

2 User-friendliness

A computer application must always be assessed in terms of its user-friendliness.

User-friendliness can be assessed on several levels:

1. The application requires a simple layout. This means that all screens are easy to read and users can easily navigate through the menus, screens and buttons.

2. The use of "keyboard and mouse functions" must be kept to a minimum. This means maximum use of barcodes, Radio Frequency Identification Device (RFID), touch screen, etc.

3. The application enables monitoring of each phase and intervention during the process.

4. The application preferably has a link to the operating theatre's planning system.

3 Security

Each user of the application is defined with an adapted profile in which rights are assigned. This allows efficient recording and reporting of all individual actions.

4 Architecture of the application

The system requires a sufficiently powerful server and a sufficiently large database to allow optimal performance. This must also include options to export and use the data.

5 Data management

The data must be easily accessible to the various users through:

1. reporting (data management system)
2. communication via a web interface, for consulting and sharing information with customers and partners of the CSD, e.g. the operation planning system, the digital patient file, the pharmacy management system, etc.
3. obtaining answers to specific questions concerning the management of the MD

6 Integration with external systems

All available process data from the appliances (sterilisers, automatic cleaning and disinfection machine, etc.) must be able to be linked to the database.
The system must allow tracking of the MD up to patient level.

7 New developments

The tracing system must allow new developments at the request of the user and/or updates on the initiative of the manufacturer.

8 Technical support

When concluding an agreement with an internal or external software developer, the technical support and maintenance by the provider must be clearly specified:

- automatic back-up,
- support in the language of the user,
- online support with the necessary security,
- training of users,
- participation in further developments,
- performance monitoring by regular updates.

XIII OUTSOURCING

1 Legal framework

The RD of 19 October 1978 regulating pharmacies and pharmaceutical stock in care institutions, amended on 29 January 2007, describes how two hospital pharmacists can draw up a mutual protocol to outsource the sterilisation of MDs.

"*A hospital pharmacist who does not possess the adequate installation and equipment for the sterilisation of reusable medical devices as referred to in the Royal Decree of 18 March 1999 concerning medical devices can outsource this sterilisation and the associated operations, either to another hospital pharmacist who does possess the adequate installation and equipment for carrying out sterilisation and who has been duly validated by him or her, or to a pharmaceutical company that holds a manufacturing licence as referred to in Article 12bis, § 1 of the Law of 25 March 1964 on medicinal products for this activity and which possesses the adequate installation and equipment for carrying out sterilisation and has been duly validated by this company.*

The outsourcing hospital pharmacist shall at minimum pass on the following information to the hospital pharmacist or the responsible person from the pharmaceutical company from whom he or she requests the preparation, sterilisation or fractionation, in order to ensure correct work:

1° the name of the hospital pharmacist requesting the outsourcing and the address and telephone number of the hospital pharmacy
2° the date of the request
3° designation of the type of preparation, sterilisation or fractionation with, where applicable, indication of the qualitative and quantitative composition

The protocol must be made out in duplicate. Together with the results of his or her work, the hospital pharmacist or the responsible person from the pharmaceutical company carrying out the preparation, sterilisation or fractionation shall send a copy of the protocol signed by him or her to the hospital pharmacist who requested the outsourcing.

This protocol shall provide no less than the following information:

1° the name of the hospital pharmacist or of the responsible person from the pharmaceutical company carrying out the sterilisation as well as the address and telephone number of the hospital pharmacist or the pharmaceutical company
2° the date of the sterilisation
3° the designation of the type of sterilisation
4° the checks carried out as well as the available data concerning the expiry date
5° the precautions to be taken, in particular measures for storage handling, use and transport

The hospital pharmacist who requested the outsourcing shall deliver the MD after affixing his or her label to it, listing the name of the patient and the expiry date. The hospital pharmacist or the responsible person from the pharmaceutical company who performed the outsourced operation must indicate the batch number and date of the operation on the packaging and, where applicable, all the information he or she considers necessary for proper storage and handling of the MD.

The hospital pharmacist who delivers the MD shall store the protocol in the medicinal products register.
The hospital pharmacist shall also sign the protocol to check the conformity of the requested operation with the protocol.
§ 5. The protocol shall be retained for a period of 10 years from delivery.

Definitions

Protocol: the document that describes the instructions clarifying the operations to be carried out, the precautions to be taken and the checks to be performed in relation to the pharmaceutical preparations, sterilisations or fractionations.

Sterilisation of reusable MD: the sterilisation of a reusable MD, including the cleaning or other processes linked to the sterilisation.

2 Recommendations

Under the aforementioned legislation, the outsourcing of certain activities, including the sterilisation of MDs, is possible between hospital pharmacists or between a hospital pharmacist and a pharmaceutical company. However, no mention is made of outsourcing to any party other than a pharmaceutical company.

This RD stipulates that the hospital pharmacist can outsource this activity if he or she does not possess the appropriate equipment. This may therefore involve the temporary or permanent inadequate capacity to safeguard the entire production.

If the hospital uses an external sterilisation service, it is still required to have a limited and central sterilisation that must satisfy the requirements of these recommendations, in order to be able to cope with unforeseen situations at all times.

The protocol between the parties must be established contractually. It shall comply with the regulations on the outsourcing and transport of infectious materials (FPS Mobility and transport, 2015).

These recommendations apply to all parties.

XIV. NON-CONVENTIONAL TRANSMISSIBLE AGENTS (PRIONS)

1 From the literature

1.1 Introduction

The risk of transmission of transmissible spongiform encephalopathies (TSE) is mainly determined by whether the patient is a high-risk patient and by the nature of the tissue with which one comes into contact.

On the one hand, high-risk patients are patients with clinical symptoms that correlate with TSE, while on the other being patients are at higher risk due to a medical treatment with cerebral substances/grafts or who have first-degree relatives with Creutzfeldt-Jakob disease (CJD). A more extensive description of this at-risk group can be found in HGR 7276 (2006).

Tissues with the greatest capacity for infection are those from the central nervous system such as brain, spinal cord, retina and facial nerve (HGR 7276, 2006).
Depending on the type of CJD, the presence of abnormal proteins is distributed over a larger number of tissues (variant form has abnormal proteins in tonsils, spleen, caecum, small intestine, lymph nodes, adrenal glands in relation to sporadic form that has these proteins mainly in the central nervous system (Peden et al., 2006)). Studies have already been published on the infectious agency of blood and there are also other studies currently underway (Ritchie et al., 2015).

The possible transmission of TSE depends on the inoculation method and the size of the inoculum. In mice, transmission takes place most efficiently after intracerebral inoculation, then intravenously, intraperitoneally or intramuscularly and finally perorally.

1.2 Transmissibility of prions via MDs

In 1977, two patients developed CJD 16 and 20 months respectively after the implantation of stereotactic electro-encephalographic indwelling electrodes for epilepsy. These electrodes had previously been used for the stereotactic exploration of a CJD patient. The CJD-inadequate “sterilisation” of these electrodes was carried out using benzene, 70% alcohol and formaldehyde vapours.

A chimpanzee in which the electrodes were subsequently implanted developed spongiform encephalopathy (Brown et al., 1992; Rutala & Weber, 2001). Other animal models also demonstrated that transmission of infection is possible via stainless steel contaminated with prions (DH, 2008).

Literature cites 5 cases of possible iatrogenic transmission as a result of neurosurgical procedures (incubation 12 - 28 months) (Brown et al., 2000; Strandberg et al., 2002). It is assumed that the routine sterilisation procedures were inadequate to eliminate the chance of infections.

The chance of transmission via a contaminated neurosurgical MD is not well known, but is certainly not 100%, despite the direct application to brain tissue (Health Canada, 2002). All transmissions via MDs occurred before 1980. On the one hand, the rare transmission of CJD via contaminated MDs reflects a limited risk, except when contact with neurological tissue is possible, while on the other it demonstrates the effectiveness of conventional cleaning and disinfection and sterilisation procedures (Rutala & Weber, 2001) (HGR 8143, 2008).

It has been recently established by histological examination of brain tissue of patients with iatrogenic CJD that amyloid-beta could also be transmitted iatrogenically. This involves a risk of iatrogenic Alzheimer's disease and cerebral amyloid angiopathy (Juanmuktane et al., 2015). Just like prion proteins, amyloid-beta can attach itself to metal surfaces and resist inactivation by formaldehyde and conventional sterilisation techniques (Fritschi et al., 2014). Prusiner et al. (2015) also recently demonstrated that human brain homogenates with alpha-synuclein prions (pathogen of multisystem atrophy (MSA)) were able to transmit this disease in cell cultures and in mice. The authors concluded that MSA is a transmissible human neurodegenerative disease.

1.3 Inactivation of prions

Prions are resistant to standard disinfection and sterilisation processes. No process per se guarantees absolute inactivation of the prions and thus a completely safe treatment of the MD (HGR 7276-2, 2006).

Only carry out invasive procedures if necessary in patients with a high or moderate risk of CJD (HGR 7276, 2006). A cerebral biopsy in a patient with a probable TSE must be avoided. If this is nevertheless necessary, stereotactic techniques must not be used under any circumstances, nor is the use of compressed-air drills permitted.
Only a **single-use MD** shall be used. However, it must be ensured that the quality of this MD is equivalent to that of reusable MDs (DH, 2007). If it is not possible to use single-use MDs, then heat-resistant MDs shall be used that can be autoclaved at 134°C or which can be treated with sodium hypochlorite or sodium hydroxide. However, none of these techniques in itself provides complete certainty regarding the elimination of prions.

To achieve inactivation of prions, careful and thorough **cleaning** is essential (DH, 2012) as soon as possible after use, to prevent the prions from drying and sealing to the surface. All MDs that could come into contact with tissues with a high risk of contamination must be cleaned with suitable equipment. All the cleaning equipment (brushes etc.) must be for single use. Correct cleaning prior to disinfection of the material is crucial and reduces the risk of infection from material contaminated with prions a hundred times. Solutions based on aldehydes must never be used, as they stabilise prions instead of inactivating them.

For an MD that is resistant to chemical treatment and which can be autoclaved, **chemical inactivation can be followed by thermal inactivation,** in accordance with HGR 7276 (2006) and WHO guidelines (2003).

Chemical inactivation

Immersion of rinsed MD in a **sodium hypochlorite solution** (NaOCl) of 20,000 ppm for 1 hour at ambient temperature.

Use caution when using NaOCl (DH, 2012):

- Do not use on open work surface due to the release of chlorine gas;
- Corrosion of metal and steel: sodium hypochlorite attacks oxidisable metals such as nickel, iron, aluminium, as well as stainless steel, but not titanium;
- Incompatible with formaldehyde, alcohols and acids;
- Rapid inactivation by protein residue;
- Always make fresh dilutions (these solutions are not stable);
- The stability of a stock solution is 2-3 weeks.

OR

Immersion of rinsed MD in a **sodium hydroxide solution** (NaOH) 2M for 1 hour at ambient temperature. This solution is prepared by dissolving 80 g of NaOH in 1 litre of distilled water.

Use caution when using NaOH (DH, 2012):

- Do not use on aluminium (oxidation), rubber or zinc;
- Damages body tissue;
- Irritates and is corrosive.

Because these inactivation processes are much more aggressive than those of normal disinfectants, the user must ask the manufacturer about the applicability of the recommended inactivation process for the various MDs to be treated.

Cleaning

After this immersion, a **cleaning process is carried out in a cleaning and disinfection appliance**. The **cleaning and disinfection appliance** is then put through a new cleaning cycle, this time empty (WHO, 2003). The cleaning process must be validated (HGR 7276-2, 2006).

Thermal inactivation

The cleaned MD then undergoes thermal inactivation by means of steam: autoclaving at 134°C in a cycle of 18 minutes or in 6 successive cycles of 3 minutes. This thermal inactivation step in itself reduces the chance of infection but does not eliminate it completely (DH, 2012). Note that the 'prion cycle', which can be found on certain bench-top vacuum autoclaves, reduces the chance of infection but also does not eliminate it completely (DH, 2012).

Many other products and procedures (alkaline and enzymatic detergents, vaporised hydrogen peroxide under vacuum (Thomas et al., 2013), plasma sterilisation) were assessed. However, for all these new methods and products there is no standardised protocol that allows a reduction in the infectious titre to be validated (Rochefort, 2008). Edgeworth et al. (2011) studied both new and conventional decontamination reagents in a cell culture-based assay that allowed all the methods to be compared with each other.

One possible benefit of these newer, less aggressive decontamination methods for MDs is that they could be used as a safe standard procedure on all types of MD (McDonnel et al.,2013). Further validation of these newer alternative decontamination methods is required before they can replace the strict WHO guidelines.

1.4 Transport of the MD

The MD is immediately taken to the CSD. Research has shown that the residual amount of protein material increases considerably when surgical MDs are stored in dry conditions for more than 15 minutes (DH, 2012).

1.5 Quarantine measures

A reusable MD used on symptomatic patients who may be suffering from CJD is placed in quarantine until it is certain that CJD was not involved. This means that the MD is placed in quarantine in a lockable dry disposable receptacle. If the diagnosis of CJD is confirmed, the MD is immersed in NaOCl and disposed of together with the receptacle. The same precautions apply in the case of asymptomatic patients with a high risk of CJD (e.g. growth hormone receptors or dura mater grafts before 1980 or family history of CJD) (Thomas et al., 2013). If the diagnosis is refuted, the MD can be reused after the standard sterilisation process.

2 Recommendations for CSD

In the event of a suspected contamination with a non-conventional transmissible agent, the MD is placed in quarantine and pretreated with an inactivating product, until the infectious status of the patient is known.

If the result is positive, the MD is destroyed.
If the result is negative, the MD goes through the standard sterilisation process.

The aforementioned pre-treatment is not routinely recommended, as it is highly corrosive (ANSM, 2011).

Taking into account the lack of documented routine sterilisation procedures that are sufficiently effective and sparing of MDs, experts strongly recommend revising the Recommendations to prevent the transmission of transmissible spongiform encephalopathies (Creutzfeldt-Jakob disease) in care institutions (HGR No. 7276-2, 2006).
Based on the new recommendations, the study group will re-examine the procedures to be introduced on this point.

XV REFERENCES

- AFS - Association Française de Stérilisation - Architecture and Sterilisation Premises - Central service 2008;16:196-293
- AFS - Association Française de Stérilisation. Les ultrasons; 2014. Internet : http://afs.asso.fr/cms/
- AFS - Association Française de Stérilisation. Architecture et locaux en stérilisation. 2002
- ANSM – Agence nationale de sécurité du médicament et des produits de santé – France; 2015. Internet :www.ansm.sante.fr
- Association Québécoise des spas. Spaulding's Classification of Medical Equipment/Devices and Required Level of Processing/Reprocessing document Best Practices for Cleaning, Disinfection, and Sterilization In All Health Care Settings (voir annexe B, [7]) The Role of chemical disinfection in the prevention of nosocomial infections (voir annexe B, [11]). Internet: http://www.associationquebecoisedesspas.com/wp-content/uploads/2012/07/AQS_Tableau-Classification-de-Spaulding.pdf.
- Brown P, Preece MA, Will RG. "Friendly fire" in medicine: hormones, homografts, and Creutzfeldt-Jakob disease. Lancet 1992;340(8810):24-7.
- Brown P, Preece M, Brandel JP, Sato T, McShane L, Zerr I, et al. Iatrogenic
- Centrale sterilisatieafdeling - College bouw ziekenhuisvoorzieningen - Bouwmaatstaven voor nieuwbouw 2003;11.
- CSS – Conseil Supérieur de la santé. Recommandations en matière de traitement du linge des institutions de soins aigus. Bruxelles: CSS 2005. Avis 8075.
- CSS – Conseil Supérieur de la Santé. Recommandations pour la prévention de la transmission des encéphalopathies spongiformes transmissibles (maladie de Creutzfeldt-Jakob) en milieu hospitalier. Bruxelles: CSS; 2006. Avis n° 7267-2.
- CSS – Conseil Supérieur de la Santé. Inactivation et sécurisation des tissus et des cellules vis-à-vis des prions, des bactéries et des virus. Partie I: Maladie de Creutzfeldt-Jakob et transplantation de tissus: risques et prévention. Bruxelles: CSS; 2008. Avis n° 8143.
- CSS - Conseil Supérieur de la Santé. Recommandations en matière d'entretien du matériel endoscopique flexible thermosensible et de prévention des infections. Bruxelles: CSS; 2010. Avis n° 8355.
- CSS – Conseil Supérieur de la santé. Révision des critères d'exclusion des donneurs de sang pour la prévention de la transmission de la maladie de Creutzfeldt-Jakob. Bruxelles: CSS; 2015. Avis n°8829.
- CSS – Conseil Supérieur de la santé. Recommandations en matière d'hygiène des mains durant les soins - Révision de 2017. Bruxelles: CSS 2017. Avis 9344.
- DH - Department of Health., Decontamination of surgical instruments in light of NICE Guidance Patient Safety and reduction of risk of transmission of CJD via interventional procedures and advice from DH Engineering and Science Advisory Committee-Prion Removal (ESAC-Pr), UK; 2007.
- DH - Department of Health Funded Research on Decontamination of Surgical Instruments. Progress Review 2008. Internet: http://www.afpp.org.uk/filegrab/dh-research-on-decontamination.pdf?ref=1393.
- DH – Department of Health. Prevention of CJD and vCJD by Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy (ACDP TSE) Subgroup . TSE agents: Safe working and the prevention of infection, UK; 2012. Internet: https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group.

- DSMH – Vereniging van Deskundigen Steriele Medische hulpmiddelen. Professionele standaard leeninstrumentarium. 2010. Internet: http://sterilisatievereniging.nl/wp-content/uploads/2015/07/2010-11-Veldnorm-Leeninstrumenten-def-1.pdf
- Edgeworth JA, Sicilia A, Linehan J, Brandner S, Jackson GS, Collinge J. A standardized comparison of commercially available prion decontamination reagents using the Standard Steel-Binding Assay. J Gen Virol 2011;92(Pt 3):718-26.
- FPS - Health, Food Chain Safety and Environment General Direction Environment List BiocidalProduct Per ProductType; 2017. Internet: http://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/liste_biocides_pdf_site_web_49.pdf.
- Fritschi SK, Cintron A, Ye L, Mahler J, Buhler A, Baumann F, et al. Abeta seeds resist inactivation by formaldehyde. Acta Neuropathol 2014;128(4):477-84.
- Galtier – La stérilisation. chapitre 5. L'inactivation des micro-organismes – Collection Pharmascopie soins et thérapies. Arnette 1996.
- Health Canada. Infection control guidelines for classic Creutzfeldt-Jakob disease (CJD) in Canada. Part of the Infection Control Guidelines Series. Canada Communicable Disease Report 2002;1-84. Internet: http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/02vol28/28S5/index.html
- Hygiènes – Guide pour le choix des désinfectants. Produits de désinfection chimique pour les dispositifs médicaux, les sols et les surfaces. 2015;22(6).
- ISP – Institut scientifique de santé publique - Modalités de validation et de contrôle des autoclaves dans le cadre de l'inactivation des déchets résultants d'utilisations confinées d'organismes génétiquement modifiés et/ou pathogènes; 2011.
- Jaunmuktane Z, Mead S, Ellis M, Wadsworth JD, Nicoll AJ, Kenny J, et al. Evidence for human transmission of amyloid-beta pathology and cerebral amyloid angiopathy. Nature 2015;525(7568):247-50.
- Kwok YL, Gralton J, McLaws M-L. face touching: a frequent habit that has implications for hand hygiene. Am J Infect Control. 2015;43(2):112-4.
- McDonnell G, Dehen C, Perrin A, Thomas V, Igel-Egalon A, Burke PA, et al. Cleaning, disinfection and sterilization of surface prion contamination. J Hosp Infect 2013;85(4):268-73.
- Peden A.H, Ritchie D.L., Head M.W., Ironside J.W. Detection and Localization of PrPSc in the Skeletal Muscle of Patients with Variant, Iatrogenic, and Sporadic Forms of Creutzfeldt-Jakob Disease. Am J Pathol. 2006 Mar; 168(3): 927–935.
- Pedersen NS, Smith E. Prion diseases: epidemiology in man. APMIS 2002;110(1):14-22.
- Pharmacopée européenne 8.0 5.1.1. - Méthodes de préparation des produits stériles
- Prusiner SB, Woerman AL, Mordes DA, Watts JC, Rampersaud R, Berry DB, et al. Evidence for alpha-synuclein prions causing multiple system atrophy in humans with parkinsonism. Proc Natl Acad Sci U S A 2015.
- Ritchie DL, Gibson SV, Abee CR, Kreil TR, Ironside JW, Brown P. Blood transmission studies of prion infectivity in the squirrel monkey (Saimiri sciureus): the Baxter study Blood transmission studies of prion infectivity in the squirrel monkey (Saimiri sciureus). 2016; Transfusion: 56,3:712–721.
- Rochefort F. Hospices civils de Lyon. Détergence et désinfection vis-à-vis du prion. Internet : http://www.sf2h.net/congres-SF2H-productions-2008/detergence-et-desinfection-des-DM_le-prion.pdf.
- Rosenberg Urs. Désinfection thermique. Le concept A_0 et son arrière-fond biologique. 2003. Forum 3-2003; p.20-3.
- Rutala WA, Weber DJ. Creutzfeldt-Jakob disease: recommendations for disinfection and sterilization. Clin Infect Dis 2001;32(9):1348-56.

- SPF – Santé publique, sécurité de la chaine alimentaire et environnement - Avis relatif à la réutilisation des dispositifs médicaux à usage unique. Conseil national des établissements hospitaliers – section « programmation & agrément » 2011; CNEH/D/324-1. Internet : http://organesdeconcertation.sante.belgique.be/sites/default/files/documents/nationale_raad_voor_ziekenhuisvoorzieningen-fr/2011_02_10_-_cneh_d_324-1_-_rutilisation_des_dispositifs_mdicaux_usage_uinique.pdf.
- SSSH – Société suisse de stérilisation hospitalière. Bonnes pratiques de retraitement des dispositifs médicaux 2016. Internet : http://www.sssh.ch/uploads/media/Bonnes_pratiques.pdf
- Thomas JG, Chenoweth CE, Sullivan SE. Iatrogenic Creutzfeldt-Jakob disease via surgical instruments. J Clin Neurosci 2013;20(9):1207-12.
- WHO – World Health Organization. WHO manual for surveillance of human transmissible spongiform encephalopathies including variant Creutzfeldt-Jakob disease, Geneva; 2003. Internet: http://www.who.int/bloodproducts/TSE-manual2003.pdf.

XVI.ANNEXES

1 Annex 1: Legal framework

1.1 Regulations

- Kingdom of Belgium. Royal Decree of 31 May 1885 on the approval of the new instructions for doctors, pharmacists and chemists. Belgian Official Gazette of 19 June 1885, No. 1885053150, p. 888888.
- Kingdom of Belgium. Royal Decree of 23 October 1964 laying down the standards to be complied with by hospitals and their services. Belgian Official Gazette of 07 November 1964, No. 1964102306, p. 11709.
- Kingdom of Belgium. Royal Decree of 19 October 1978 regulating pharmacies and medicinal stocks in care institutions. Belgian Official Gazette of 23 February 2007, No. 2007022210, p. 8840.
- Kingdom of Belgium. Royal Decree of 15 December 1978 laying down special standards for university hospitals and hospital services. Belgian Official Gazette of 4 July 1979, p. 7518.
- Kingdom of Belgium. Royal Decree of 4 March 1991 laying down the standards to be met by a hospital pharmacist in order to be accredited. Belgian Official Gazette of 23 March 1991, No. 19991025060, p. 5965.
- Kingdom of Belgium. Royal Decree of 18 March 1999 on medical devices. Belgian Official Gazette of 14 April 1999, No. 1999022270, p. 12105.
- Kingdom of Belgium. Royal Decree of 29 January 2007 amending the Royal Decree of 19 October 1978 laying down rules for pharmacies and pharmaceutical stocks in care institutions. Belgian Official Gazette of 31 October 1978, No. 1978101902, p. 13251.
- Kingdom of Belgium. Royal Decree of 26 April 2007 amending the Royal Decree of 23 October 1964 laying down the standards to be complied with by hospitals and their services. Belgian Official Gazette of 7 June 2007, No. 20070227792, p. 30947.
- EC - Council of the European Union - Regulation on the proposal for a regulation of the European Parliament and of the Council concerning medical devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.
- Directive 90/385/EEC (active implantable medical devices); 1990.
- **Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; 1993.**
- Directive 98/79/EC on in vitro diagnostic medical devices; 1998.
- Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

1.2 Standards

- **NEN-EN 285**: Sterilization - Steam sterilizers - Large sterilizers.
- **NEN-EN 867-4**: Non-biological systems for use in sterilizers - Part 4: Specification for indicators as an alternative to the Bowie and Dick test for the detection of steam penetration.
- **NEN-EN 868-2:** Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods.
- **NEN-EN 868-3:** Packaging for terminally sterilized medical devices - Part 3: Paper for use in the manufacture of paper bags (specified in NEN-EN 864-4) and in the manufacture of pouches and reels (specified in NEN-EN 868-5) - Requirements and test methods.
- **NEN-EN 868-4:** Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods.
- **NEN-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.
- **NEN-EN 868-6**: Packaging for terminally sterilized medical devices - Part 6: paper for low temperature sterilization processes - Requirements and test methods.
- **NEN-EN 868-7:** Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods.
- **NEN-EN 868-8**: Packaging for terminally sterilized medical devices - Part 8: Reusable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods.
- **NEN-ISO 9001**: Quality management systems/requirements.
- **NEN EN 1005-1**: Safety of machinery - Human physical performance - Terms and definitions.
- **NEN-EN-ISO 11138-1**: Sterilization of health care products - Biological indicators - Part 1: General requirements. Replaces the EN 866 series.
- **NPR-ISO/TS 11139**: Sterilization of health care products - Vocabulary.
- **NEN-EN-ISO 11140-1**: Sterilization of health care products - Chemical indicators - Part 1: General requirements - Replaces EN 867-1.
- **NEN-EN-ISO 11140-3**: Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test.
- **NEN-EN ISO 11140-4**: Sterilization of health care products - Chemical indicators - Part 4 - Class 2 indicators as an alternative to Bowie and Dick test for detection of steam penetration.
- **NEN-EN-ISO 11140-5**: Sterilization of health care products - Chemical indicators - Part 5 - Class 2 indicators as an alternative to Bowie and Dick-type air removal test sheets and packs
- **ISO 11228-1:** Manual handling - Lifting and carrying.
- **NEN-EN-ISO 11607-1** Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
- **NEN-EN-ISO 11607-2:** Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
- **NEN-EN 13060:** Small steam sterilisers.
- **NEN-EN-ISO 13485:** Medical devices - Quality management systems - Requirements for regulatory purposes.
- **NEN EN 14222**: Stainless steel shell boilers.
- **NEN-ISO 14644-1:** Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration.

- **NEN-EN-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.
- **NEN-EN-ISO 15223-1:** Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
- **NEN-EN-ISO 15883-1:** Washer-disinfectors - Part 1: General requirements, terms and definitions and tests.
- **NEN-EN-ISO 15883-2**: Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
- **NEN-EN-ISO 16664:** Gas analysis - Handling of calibration gases and gas mixtures - Guidelines.
- **NPR-CEN-ISO/TS 16775**: Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2.
- **NEN-EN-ISO 17664**: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- **NEN-EN-ISO 17665-1:** Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- **NPR-CEN-ISO/TS 17665-2:** Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1.
- **Standard NF S 90-351**: *Clean rooms and related controlled environments in medical establishments.*

2 Annex 2: Minority position of Yvon Bories

I start from the concept of sterilisation, several scientific findings, practical experiences and a common naive belief and I conclude:

- either we change the concept
- or, to guarantee the sterility of medical devices (MDs), it is absolutely necessary to wear industrially clean gloves when packing high-quality disinfected MDs.

The sterility of the MD is guaranteed if the actual sterilisation is preceded by high-quality disinfection and this disinfection is preceded by high-quality cleaning. After high-quality cleaning (1) the MDs are free from non-living organic contaminants. After high-quality disinfection (2) the MDs are free from all metabolically active bacteria at a minimum disinfection level Ao = 600 and after a recommended disinfection level Ao = 3,000 free from all but traces of any activatable microbiota.

D. Pittet states the following in 'The Lancet Infectious Diseases 1/2006; 6(10):641-52': "The total number of bacteria on the hands of health professionals varies from 3.9×10^4 to 4.6×10^6 CFU[15]/cm²".
Hand contact leads to transmission of skin lipids, flakes of skin, epithelial cells, sweat, sebum, etc. and also to the transmission of high numbers of bacteria, skin viruses, yeasts, fungi and mites.

[15] CFU: Colony-forming units

After a decade of national hand hygiene campaigns, compliance for hand hygiene is theoretically around 70%. Hand hygiene is mainly directed at transient flora. And we regularly assume incorrectly that with good hand hygiene the transmission of microbiota is very small and that consequently, in theory, good hand hygiene is generally sufficient to prevent healthcare-associated infections. We view humans too much as complex organisms, with a commensal microbiota as an epiphenomenon, on Earth. But if, like Copernicus, we were to reverse this picture, we would see a different reality: a world of protozoa with humanity as epiphenomenon. The skin is living matter and there is no multicellular living matter without protozoa: all multicellular life is composed life. In the context of sterilisation, the distinction between commensal microbiota and other microbiota is irrelevant.

If (1) and (2) are required, then allowing unprotected hand contact just prior to the actual sterilisation is a logical error.
In other words, saying that these contaminations do not compromise the sterilisation process and require prior high-quality disinfection is at odds with basic logic - if these contaminations do not compromise the sterilisation process then prior high-quality disinfection is not required, and since this is in fact required in the current understanding, these contaminations do indeed compromise the sterilisation process and we must then prevent these contaminations by wearing industrially clean gloves when handling these MDs. Gloves, disposable, which we can take out of the packaging one by one by the cuff… If we do not change the common concept of sterilisation, then the wearing of gloves when handling high-quality disinfected MDs is not a recommendation but a logical requirement.

References

1. Thermal Disinfection – The Ao Concept and the Biological Background, Urs Rosenberg, Borer Chemie AG, Switzerland
2. Schuermans, A. et al.: Sensibilisatiecampagne handhygiëne door de Regionale Werkgroep voor Ziekenhuishygiëne Vlaams-Brabant en Limburg. NOSO-info, vol. VIII nr. 4, 2004
3. Pittet D., et al Evidence-based model for hand transmission during patient care and the role of improved practices. The Lancet Infectious Diseases 1/2006; 6(10):641-52.
4. Bories, Y. en Catry, B. Instrumenten na manipulatie met blote handen zijn, ondanks een gevalideerde sterilisatie, niet gegarandeerd steriel, Yvo Bories en Boudewijn Catry, NOSO-info, vol. XIX n°4, 2015
5. Bories, Y. Waarom een oproep voor een nieuwe zorghygiënedenkkader, nog niet uitgegeven werk
6. Sintubin, M. De wetenschap van de aarde – over een levende planeet, Acco.

3 Annex 3: FMECA method

One of the methods for assessing potential malfunctions is the FMECA method (**F**ailure Mode, Effects and Criticality Analysis).

This method always consists of a **qualitative** analysis:

- analysis of the malfunction **causes**
- analysis of the malfunction **forms**
- analysis of the malfunction **effects**

Followed by a quantitative evaluation:

- evaluation of the **frequency** of these malfunctions
- evaluation of the **seriousness** of these malfunctions
- evaluation of the **probability** of these malfunctions remaining unnoticed

It is important to include all possible actors (technology, CSD staff, customers, management) in this risk analysis for sterilisation.
The following calculation is a simple way of measuring the risk level of an event:

C = G x F x D

C: Criticality (risk level)
G: Gravity
F: Frequency
D: Detection

The calculated risk level allows the corrective or preventive measures to be taken as a priority to be chosen, from a collective vision and with the consensus of the various parties involved.

4 Annex 4: Calculating the sterilisation value F0 and equivalence of the cycles for sterilisation with saturated steam

For the **biological indicator** to validate sterilisation with saturated steam, the spores of *Bacillus stearothermophilus* of reference strains are used as a strain (ATCC 12980 pe) (Galtier, Eur. Pharmacopoeia).

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

In accordance with the two sterilisation laws:

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

With a contamination of 10^6 germs, 6 x 1.5 min = 9 min is needed to obtain 1 germ.
Since the SAL is 10^{-6} (SAL means the chance of 1 in 10^6 of finding a germ), 6 x 1.5 min is needed to reach the SAL.
Conclusion: at 120°C 18 min is needed to bring the contamination from 10^6 to the SAL.

2. Z = 10°C means that if the temperature rises 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 the cycles at different temperatures with each other and assess their equivalence, the duration must be compared with the reference temperature: the **lethality level L** is used for this.

"L": this is the relationship between the sterilisation effectiveness of a treatment at a given temperature in relation to that of a treatment at a reference temperature, either 120°C (UK) or 250°F (121.1°C America).

A 120°C, L = 1 (Anglo-Saxon table AS)	A 120°C, L = 0.774
A 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: this is the time in minutes during which sterilisation takes place at a temperature of 120°C (AS) or 121°C (US), with a thermal destruction value of Z = 10°C to achieve a sterilising effect.

Note: check in the programmes of the sterilisers whether the Anglo-Saxon or American reference is used to calculate F_0.

Calculating the sterilisation value of a number of cycles in relation 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 (US)

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.

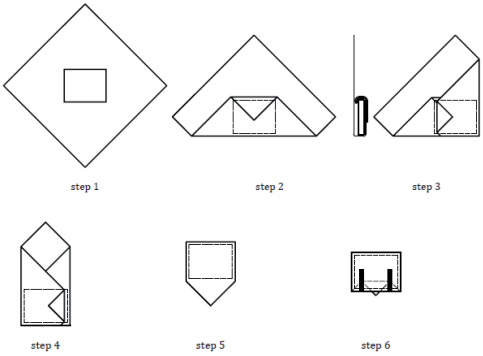
5 Annex 5: Packaging methods (NPR-CEN-ISO/TS 16775)

NBN

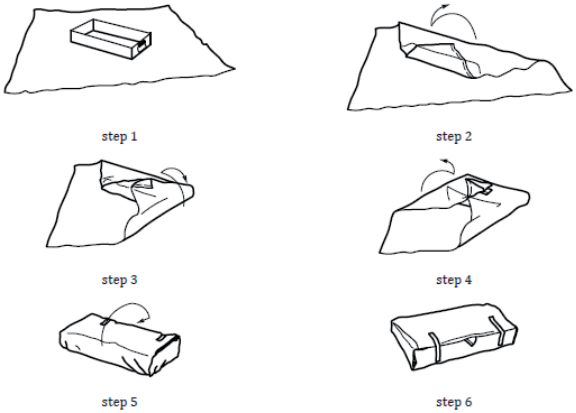
The Bureau of Normalization (NBN; Bureau voor Normalisatie; Bureau de normalisation) has given us permission to publish the figures from CEN ISO/TS 16775:2014.
The technical specification CEN ISO/TS 16775:2014 can be obtained from the NBN (www.nbn.be)

A. Envelope method

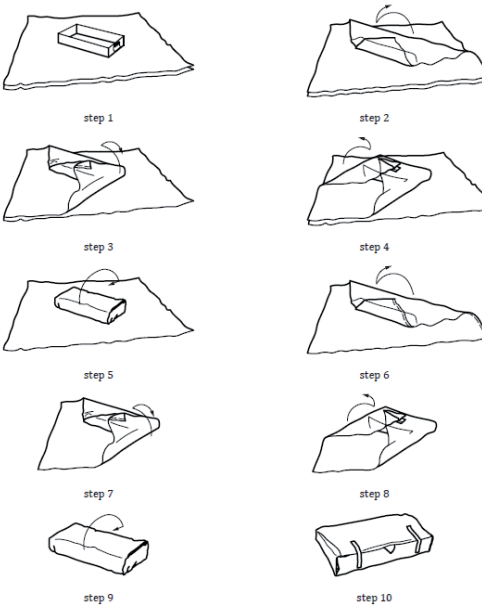
1. Envelope method step 1 to step 6



2. Envelope method simultaneous double wrapping

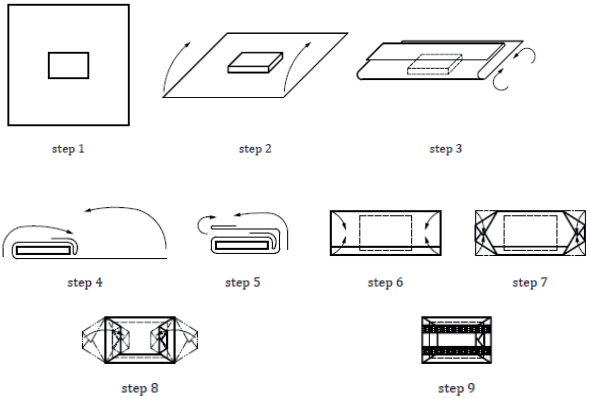


3. Envelope method sequential double wrapping

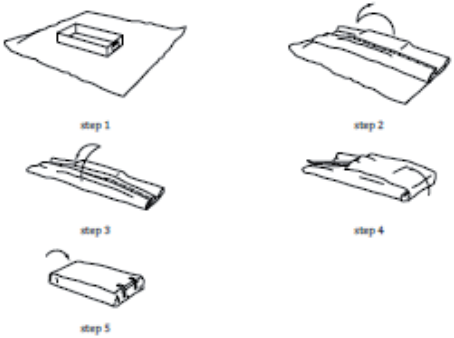


B. <u>Parallel packaging / square fold method wrapping</u>

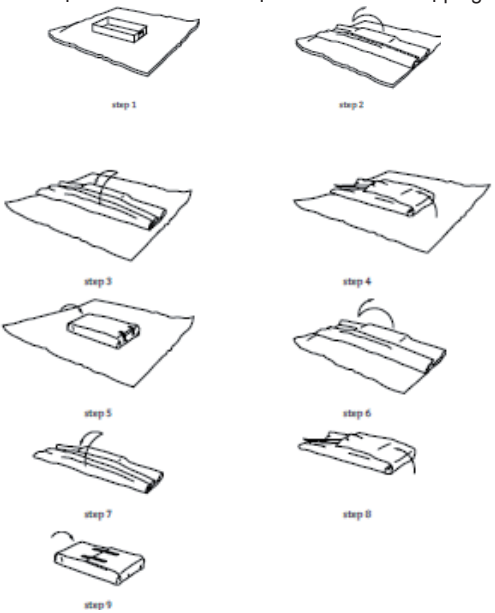
1. Parallel packaging



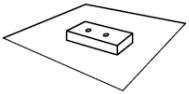
2. Square fold method simultaneous double wrapping



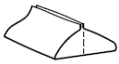
3. Square fold method sequential double wrapping



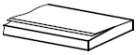
C. Pasteur or roll method



step 1



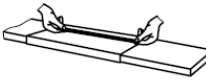
step 2



step 3

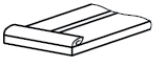
step 4

step 5



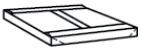
Hands position for step 4,5,6

step 6

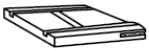


step 7

step 8



step 9



step 10

6 Annex 6: Indicators

The chemical indicators or indicator systems described in part 3 of standard ISO 11140 are intended for the following applications:

a) to be able to distinguish between treated and untreated items,
b) in specific tests and/or processes, e.g. the Bowie-Dick test,
c) positioning within individual loads to check whether the process parameters are being achieved and/or the respective parameter(s) are being achieve at the location position.

The six indicator types described in the main part of this section of ISO standard 11140 are grouped according to their performance requirements. Table 6 describes three categories based on the intended use. The chemical indicators are further broken down by category according to the sterilisation process for which they were designed. These categories have no hierarchical significance. Reaching the end point of the chemical indicator must not be regarded as an indication of reaching an acceptable level of sterility, but as one of the many factors to be taken into account when assessing the acceptability of a sterilisation process.

Table 6 - Categories according to intended use

Intended use		Class	Category	Description (intended use)
Indication of exposure to a process to be able to distinguish untreated from treated items, and/or indication of serious shortcomings in a sterilisation process		1	e1	"Exposure" or process indicator Requirements according to class 1
Indicators intended for specific applications, e.g. Bowie & Dick-type test		2	s2	"Special" indicator (e.g. Bowie-Dick) Requirements in accordance with ISO 11140-3, ISO 11140-4 and ISO 11140-5
Indicators to be placed within individual loads to assess whether the critical process variables are being reached at the position location	This indicator only reacts to one critical process variable	3	i3	"Internal" indicator Unique variable indicator Requirements according to class 3
	This indicator reacts to several critical process variables	4	i4	"Internal" indicator Multivariable indicator Requirements according to class 4
	This indicator reacts to all critical process variables	5	i5	"Internal" indicator Integrator Requirements according to class 5
	This indicator reacts to all 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 that the unit was directly exposed to the sterilisation process and to distinguish between the treated and untreated units. These are designed to react to one or more critical process variables.

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

Class 3: unique variable indicators
A unique variable indicator is designed to react to one of the critical variables and is intended to indicate exposure to a sterilisation process in the light of a reference value determined for the chosen variable.

Class 4: multivariable indicators
A multivariable indicator is designed to react to two or more critical variables and is intended to highlight exposure to a sterilisation cycle in the light of the reference values determined for the chosen variables.

Class 5: integration indicators
Integration indicators are designed to react to all critical variables. The reference values are established so that they are equivalent to or higher than the performance requirements determined in the ISO 11138 series of standards for biological indicators.

Class 6: emulation indicators
Emulation indicators are cycle verification indicators designed to react to all critical variables for specific sterilisation cycles. The reference values are determined using the critical variables of the specific sterilisation process (standard NEN-EN-ISO11140-1).

XVII 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.

BALLYN Geert	Nursing, sterilisation	VSZ, AZ Delta
BOETS Sandra	Nursing, sterilisation	RZ Tienen
BORIES Yvon	Nursing, hospital hygiene	NVKVV, AZ Nikolaas
BROSENS Patricia	Hospital pharmacy, sterilisation	
CARPINTERO Reyes	Nursing, hospital hygiene	CHIREC
COMPERE Alain	Nursing, hospital hygiene	Bois abbaye Seraing
DE LA CHARLERIE Isabelle	Nursing, sterilisation	ASTER, CHR-Namur
DELHAUTER Blaise	Hospital pharmacy, sterilisation	CHR Citadelle Liège
DE MAITER Guido	Nursing, hospital hygiene	AZ Groeninge, NVKVV
DEMEULDRE Pierre-François	hospital pharmacy, sterilisation	CHU-Liège
HENROTIN Krist	Nursing, sterilisation	UZ Gent
LEBLUS Florence	Nursing, hospital hygiene	CHU-Tivoli
MEERT Wouter	Nursing, sterilisation	UZ Leuven
MUTSERS Jacques	Nursing, hospital hygiene	CHU-ULG Liège
SAEGEMAN Veroniek	Medicine, clinical biology, hospital hygiene	UZ Leuven
SWITTEN Nathalie	Hospital pharmacy, sterilisation	Jessa ziekenhuis
ZORZI Willy	Infectious diseases, prions	ULG Liège

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

DREESEN Mira	Hospital pharmacy, sterilisation	UZ Leuven
EVEN Alain-Michel	Nursing, sterilisation	ASTER, CHA Libramont

The following administrations and/or ministerial cabinets were heard:

DUMONT Bénédicte	Pharmacy, inspection	FAMHP
GAY Emmanuelle	Pharmacy, inspection	FAMHP
GEERAETS Els	Laywer	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.css-hgr.be

federal public service
HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT