GUIDANCE ON THE PRINCIPLES OF STERILIZATION PROCEDURES UTILISED IN HEALTH CARE FACILITIES IN THE ERHA

Eastern Regional Health Authority
Infection Control Advisory Committee

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Guidance on the Principles of Sterilization Procedures utilised in Health Care Facilities in the ERHA.

1.0 INTRODUCTION

This document offers guidance on the principles of sterilization and related processes utilised on medical equipment in Health care facilities in the ERHA. Also included is a list of the relevant EU and Irish legislation combined with European, Irish and British standards and guidelines.

Definitions:

- **Sterilization** is a process that is undertaken to render a load or instrument sterile.
- **Sterile** is the condition of a load item that is free from viable micro-organisms.
- **Sterilization Process** is the complete set of procedures required for the sterilization of a load, including the operating cycle and any treatment of the load before or after the operating cycle.
- **Disinfection** is a process used to reduce the number of viable micro-organisms in a load, minimizing the hazard of infection. It may not necessarily inactivate some viruses and bacterial spores.
- **High Level Disinfection**, (for example, using chemicals) is an increased level of disinfection, but sterility cannot be guaranteed.
- **Washing or Cleaning** is a process to remove contaminants (e.g. dust, soil, chemical residue, pyrogens, large number of micro-organisms and organic material). It is a prerequisite to disinfection or sterilization.
- **Decontamination** is the removal and destruction of infectious agents from instruments that are intended to be used on patients. There are two stages in this process;
  1. Washing
  2. Disinfection or sterilization.

  The type of process utilised will depend on the instrument and its intended use. Inadequate decontamination can result in a number of problems:
  - Transfer of micro-organisms that may cause infection.
  - Transfer of particulate matter that can result in granuloma.
  - Transfer of bacterial endotoxins that can cause inflammation.
  - Transfer of prions which may cause CJD.
  - Transfer of foreign proteins that can cause adverse reactions.

  Safe and effective decontaminating processing of reusable equipment prevents risk of transfer of infection to patients and staff.
  C.S.S.D. is a Central Sterile Supply Department.

References:

- HTM 2010 (Appendix D, page 14).
- Russell et al 1999 (Appendix D, page15).

2.0 MANAGEMENT

It is important that a clear management structure is in place to supervise the decontamination processes utilised in a health care facility. There should be a formal structure overseen by Senior Administrative and professional personnel. At all levels of the

management structure, it must be clear to those involved, what their role and responsibilities are. There should be written protocols developed in consultation with staff which are easily available to all relevant personnel.

Ensuring the implementation of a quality decontamination system is the responsibility of management in the Health care facility. The success of this quality system will depend on how effective the management structure is and the clarity of the system components to those implementing it..

Generally such a quality system will be co-ordinated in a Central Sterile Supply Department (CSSD). Good communication with other hospital departments and personnel such as medical and nursing staff is important to ensure effective running of the CSSD. Manufacturers are legally responsible for providing directions on the decontamination of reusable equipment (Medical Devices Directorate 93/42/EEC). Since this directive came into force, medical devices may be put on the market only if the manufacturer can claim that the equipment meets the relevant 'essential requirements' of the Directive. This means that the equipment is as safe as possible and is fit for the intended purpose. These devices must show the "CE" mark to signify the claims of conformity and this enables the device to be sold throughout the EU without further controls.

The Infection Control Team, where available should be involved in deciding the recommended sterilization/decontamination process for all clinical equipment in a health care facility.

There are a number of areas that need to be addressed by management.

2.1 Building Design.

New health care buildings should be designed with the requirements of the decontamination processes in mind and older building adapted as necessary. Some of the desirable features are listed below:

1. New hospitals and major health care facilities should include a properly designed Central Sterile Supply Department (CSSD).
2. All rooms used for surgical procedures should be of sufficient size to enable proper cleaning and safe use of equipment. We recommend that all institutions have, where practicable, a CSSD near but separate from the theatres and rooms used for minor surgery.
   The typical workflow (in one direction) for surgical instruments is as follows:
   - Sorting, washing and drying.
   - Inspection.
   - Sterilization
   - Transfer to sterile goods store.
   - Distribution to wards/departments.
3. Wall, floors and all work surfaces must be easily cleanable.
4. All clinical equipment should be capable of sterilization or high levels disinfection and be used for the intended purposes.
5. There should be a safe place for storing heath care risk waste.

2.2 Training of Operatives.

Staff need documented training to ensure they are competent to carry out decontamination processes. All operators must receive detailed training in procedures that they will be expected to carry out and have a good understanding of general decontamination principles. Staff working in the CSSD or with particular responsibilities for decontamination procedures should attend relevant courses and attain relevant competency. Training should include all areas mentioned in the following Section 2.3.

2.3 Best Practice and Procedures in CSSD Departments.

Best practice and procedures should include:

1. Appropriate staff handwashing. Cuts and abrasions should be covered with waterproof dressings.
2. Use of personnel protective clothing e.g. Gloves, plastic aprons and visors when handling all items, particularly bloodstained and sharp instruments.
3. Segregation of contaminated and decontaminated instruments.
4. Known high risk items should be decontaminated as soon as possible with minimum handling.
5. Automatic washers should be used to clean medical devices pre-processing where possible. Manual cleaning of medical devices should only be used where there is no alternative e.g. thermo labile equipment such as a some fibre-optics and electronic equipment.
6. The proper management of instruments; e.g. forceps and scissors require opening before washing to ensure proper cleaning, followed by disinfection or sterilization.
7. Inspection and packaging; Ensure that appropriate packaging is used and that it is intact pre-sterilization.
8. Correct use of sterile equipment and correct handling of sterile packs to ensure sterility is not compromised.
9. Testing and verification of decontaminating equipment as laid down in the relevant standards.
10. Traceability of reprocessed medical devices.
11. Appropriate storage of sterile instruments and associated record keeping.
12. Record keeping; . Records need to be kept of:
    a. All staff training.
    b. Repairs, servicing, and validation of all sterilizing equipment.
    c. All validated loads with unique traceable identification of adequately sterilised equipment.
    d. Records need to be kept for a period agreed by the Health Authorities.
13. Stock control. There needs to be a system of storage and supervision of all instruments to ensure that all stored instruments are kept in appropriate conditions for the correct period of time. All sterilized items should be labelled with expiration dates. A protocol should exist to ensure that the oldest items are used first.
14. Transport. Staff must be made aware of the regulation governing the transport of instruments.
15. Immunisation: All staff handling potentially contaminated instruments or equipment should be immunised against Hepatitis B.

2.4 Validation of Decontaminating Processes.

Validation demonstrates that the physical conditions necessary for sterilization (temperature, pressure, time) or disinfection are achieved. It includes:-

(i) Commissioning tests (installation checks and tests on new decontaminating equipment).
(ii) Performance qualification tests.
(iii) Routine periodic testing to ensure the decontaminating equipment is working properly.

A system is required to ensure comprehensive records of the decontamination process are kept. There should be formal procedures in place for the validation and monitoring of decontaminating equipment e.g (autoclaves). Records are required for each cycle. It is important that health care facilities can provide evidence of sterility.

The validating and monitoring processes as provided under European and Irish standards (See Appendix A & C) should be complied with to ensure sterility. For British Standards as further reference, see Appendix B.

(i) Commissioning tests provides evidence that equipment has been supplied and installed in accordance with the specifications. Commissioning is carried out after a piece of equipment is installed in the place of its use. Commissioning tests are carried out after installation of the piece of equipment and should be done, if possible, by a qualified person not employed by the company supplying the equipment.

(ii) Performance Qualification Tests are carried out to show that the equipment can sterilize/disinfect more difficult loads to the required standard. These tests need to be done regularly as set out in the relevant standards.

References:

- Performance Qualification for sterilizing equipment,
  - ISO 13683 (Appendix C).
  - EN 13060 (Appendix C).
  - HTM 2010 (Appendix D).

(iii) Routine Periodic Testing.

These tests are carried out daily, weekly, quarterly and yearly and demonstrate that the sterilizer continues to work properly. The new standard (EN 13060) for the use of bench top autoclaves and the standards for large autoclaves (EN 285, ISO 13683, I.S.EN 12347) give the details of these tests. These tests are also elaborated in the UK guidance document, HTM 2010. The daily and weekly tests can be performed by the user but the quarterly and annual tests will need to be done by a qualified person (Test Person).

Pressure Vessels such as autoclaves, which are steam generating, must have a pressure vessel check done every 14 months by a competent person (Factories Act Ireland 1955, Appendix D).

2.5 Maintenance of decontaminating (Sterilizing) Equipment.

All sterilizing equipment should be subject to a planned maintenance programme as recommended by the supplier and by the relevant standards. A planned programme of maintenance should be agreed and responsibility allocated to specific personnel. Management should ensure complete compliance with this planned programme.

Management should ensure that records are kept of all validation, testing and maintenance of sterilizing equipment. The recording system should ensure that the records are:

- Legible and dated.
- Written at the time the tests are carried out.
- Maintained in an orderly fashion and show the proper traceability of processes undertaken.
- Identify the person recording the data and demonstrate that processes were undertaken according to prescribed standards.

2.6 Traceability.

A decontamination auditable system should be in place. This would ensure that any decontaminated instrument can be traced back to a particular sterilization cycle and a record on the patient's chart of each instrument's decontaminating batch number. Ideally the tracing system should make it possible to trace sets of instruments utilized on individual patients. All stages of the sterilization/decontamination process should be documented.

2.7 Audit.

There should be formal external periodic auditing of the decontamination processes utilised in a Health care facility. This will assess whether decontaminating processes in place are working to a satisfactory level. The external audit is recommended on an annual basis. This audit should focus on how the processes are being carried out as well as testing the sterilizing equipment. A programme of internal audits is also recommended, performed by staff appropriately trained in conducting audits.

APPENDIX A

IRISH STANDARDS:

STANDARD NUMBER	TITLE	
I.S. EN 552	STERILISATION OF MEDICAL DEVICES - VALIDATION AND ROUTINE CONTROL OF STERILISATION BY IRRADIATION	1994
I.S. EN 285	STERILISATION - STEAM STERILISERS - LARGE STERILISERS	1997
I.S. EN 550	STERILISATION OF MEDICAL DEVICES - VALIDATION AND ROUTINE CONTROL OF ETHYLENE OXIDE STERILISATION	1994
I.S. EN 552	STERILISATION OF MEDICAL DEVICES - VALIDATION AND ROUTINE CONTROL OF STERILISATION BY IRRADIATION	1994
I.S. EN 554	STERILISATION OF MEDICAL DEVICES - VALIDATION AND ROUTINE CONTROL OF STERILISATION BY MOIST HEAT	1994
I.S. EN 556	STERILISATION OF MEDICAL DEVICES - REQUIREMENTS FOR TERMINALLY - STERILISED MEDICAL DEVICES TO BE LABELLED "STERILE"	2001
I.S. EN 556-1	STERILISATION OF MEDICAL DEVICES - REQUIREMENTS FOR MEDICAL DEVICES TO BE DESIGNATED STERILE - PART 1:REQUIREMENTS FOR TERMINALLY STERILISED MEDICAL DEVICES	2002
I.S. EN 866-1	BIOLOGICAL SYSTEMS FOR TESTING STERILISERS AND STERILISATION PROCESS - GENERAL REQUIREMENTS	1997
I.S. EN 866-2	BIOLOGICAL SYSTEMS FOR TESTING STERILISERS AND STERILISATION PROCESSES-PARTICULAR SYSTEMS FOR USE IN ETHYLENE OXIDE STERILISERS	1997
I.S. EN 866-3	BIOLOGICAL SYSTEMS FOR TESTING STERILISERS AND STERILISATION PROCESSES- PARTICULAR SYSTEMS FOR USE IN MOIST HEAT STERILISERS	1997
I.S. EN 866-4	BIOLOGICAL SYSTEMS FOR TESTING STERILISERS AND STERILISATION PROCESSES- PART 4 - PARTICULAR SYSTEMS FOR USE IN IRRADIATION STERILISERS	2000
I.S. EN 866-5	BIOLOGICAL SYSTEMS FOR TESTING STERILISERS AND STERILISATION PROCESSES- PART 5 - PARTICULAR SYSTEMS FOR USE IN LOW TEMPERATURE STEAM AND FORMALDEHYDE STERILISERS	2000
I.S. EN 866-6	BIOLOGICAL SYSTEMS FOR TESTING STERILISERS AND STERILISATION PROCESSES- PART 6 - PARTICULAR SYSTEMS FOR USE IN DRY HEAT STERILISERS	2000
I.S. EN 866-7	BIOLOGICAL SYSTEMS FOR TESTING STERILISERS AND STERILISATION PROCESSES- PART 7 - PARTICULAR SYSTEMS FOR SELF-CONTAINED BIOLOGICAL INDICATOR SYSTEMS FOR USE IN MOIST HEAT STERILISERS	2000
I.S. EN 866-8	BIOLOGICAL SYSTEMS FOR TESTING STERILISERS AND STERILISATION PROCESSES- PART 8 - PARTICULAR SYSTEMS FOR SELF-CONTAINED BIOLOGICAL INDICATOR SYSTEMS FOR USE IN ETHYLENE OXIDE STERILISERS	2000
I.S. EN 868-2	PACKAGING MATERIALS AND SYSTEMS FOR MEDICAL DEVICES WHICH ARE TO BE STERILISED - STERILISATION WRAP - REQUIREMENTS AND TEST METHODS	1999
I.S. EN 868-6	PACKAGING MATERIALS AND SYSTEMS FOR MEDICAL DEVICES WHICH ARE TO BE STERILISED - PAPER FOR THE MANUFACTURES OF PACKS FOR MEDICAL USE FOR STERILISATION BY ETHYLENE OXIDE OR IRRADIATION - REQUIREMENTS AND TEST METHODS	1999
I.S. EN 868-7	PACKAGING MATERIALS AND SYSTEMS FOR MEDICAL DEVICES WHICH ARE TO BE STERILISED - ADHESIVE COATED PAPER FOR THE MANUFACTURE OF HEAT SEALABLE PACKS FOR MEDICAL USE FOR STERILISATION BY ETHYLENE OXIDE OR IRRADIATION - REQUIREMENTS AND TEST METHODS	1999
I.S. EN 868-8	PACKAGING MATERIALS AND SYSTEMS FOR MEDICAL DEVICES WHICH ARE TO BE STERILISED - RE-USABLE STERILISATION CONTAINERS FOR STEAM STERILISERS CONFORMING TO EN 285 - REQUIREMENTS AND TEST METHODS	1999
I.S. EN 1174-1	STERILISATION OF MEDICAL DEVICES - ESTIMATION OF THE POPULATION OF MICRO-ORGANISMS ON PRODUCT - PART 1:REQUIREMENTS	1996
I.S. EN 1174-2	STERILISATION OF MEDICAL DEVICES - ESTIMATION OF THE POPULATION	1997

	OF MICRO-ORGANISMS ON PRODUCT - PART 2: GUIDANCE	
I.S. EN 1174-3	STERILISATION OF MEDICAL DEVICES - ESTIMATION OF THE POPULATION OF MICRO-ORGANISMS ON PRODUCT - PART 3: GUIDE TO THE METHODS FOR VALIDATION OF MICROBIOLOGICAL TECHNIQUES	1997
I.S. EN ISO 10993-7	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - ETHYLENE OXIDE STERILISATION RESIDUALS	1996
I.S. EN ISO 11737-2	STERILISATION OF MEDICAL DEVICES - MICROBIOLOGICAL METHODS - PART 2 - TESTS OF STERILITY PERFORMED IN THE VALIDATION OF A STERILISATION PROCESS	2000
I.S. EN ISO 13402	SURGICAL AND DENTAL HAND INSTRUMENTS - DETERMINATION OF RESISTANCE AGAINST AUTOCLAVING, CORROSION AND THERMAL EXPOSURE	2000
I.S. EN ISO 14160	STERILISATION OF SINGLE-USE MEDICAL DEVICES INCORPORATING MATERIALS OF ANIMAL ORIGIN - VALIDATION AND ROUTINE CONTROL OF STERILISATION BY LIQUID CHEMICAL STERILANTS	1998
I.S. EN ISO 14161	STERILISATION OF HEALTH CARE PRODUCT - BIOLOGICAL INDICATORS - GUIDANCE FOR THE SELECTION USE AND INTERPRETATION OF RESULTS	2001
I.S. EN ISO 14937	STERILISATION OF HEALTH CARE PRODUCTS - GENERAL REQUIREMENTS FOR CHARACTERISATION OF A STERILISATION PROCESS FOR MEDICAL DEVICES AND ROUTINE CONTROL OF A STERILISATION PROCESS FOR MEDICAL DEVICES	2000
I.S. EN 12347	BIOTECHNOLOGY-PERFORMANCE CRITERIA FOR STEAM STERILIZERS AND AUTOCLAVES	1998
I.S. EN 1422	STERILIZERS FOR MEDICAL PURPOSES – ETHYLENE OXIDE STERILIZER-SPECIFICATIONS	1997

APPENDIX B

BRITISH STANDARDS:

STANDARD NUMBER	TITLE
BS 2646:1988	AUTOCLAVES FOR STERILIZATION IN LABORATORIES
BS 3421:1966	PERFORMANCE OF ELECTRICALLY HEATED STERILIZING OVENS
BS 3970-1:1990	STERILIZING AND DISINFECTING EQUIPMENT FOR MEDICAL PRODUCTS. SPECIFICATION FOR GENERAL REQUIREMENTS
BS 3970-2:1991	STERILIZING AND DISINFECTING EQUIPMENT FOR MEDICAL PRODUCTS. SPECIFICATION FOR STEAM STERILIZERS FOR AQUEOUS FLUIDS IN SEALED RIGID CONTAINERS
BS 3970-4:1990	STERILIZING AND DISINFECTING EQUIPMENT FOR MEDICAL PRODUCTS. SPECIFICATION FOR TRANSPORTABLE STEAM STERILIZERS FOR UNWRAPPED INSTRUMENTS AND UTENSILS
BS 3970-5:1990	STERILIZING AND DISINFECTING EQUIPMENT FOR MEDICAL PRODUCTS. SPECIFICATION FOR LOW TEMPERATURE STEAM DISINFECTORS
BS 3970-6:1993	STERILIZING AND DISINFECTING EQUIPMENT FOR MEDICAL PRODUCTS. SPECIFICATION FOR STERILIZERS USING LOW-TEMPERATURE STEAM WITH FORMALDEHYDE
BS 3970:PART 1:1966	SPECIFICATION FOR STEAM STERILIZERS. STERILIZERS FOR POROUS LOADS
BS 3970:PART 2:1966	SPECIFICATION FOR STEAM STERILIZERS. STERILIZERS FOR BOTTLED FLUIDS
BS 3970:PART 3:1990	STERILIZING AND DISINFECTING EQUIPMENT FOR MEDICAL PRODUCTS. SPECIFICATION FOR STEAM STERILIZERS FOR WRAPPED GOODS AND POROUS LOADS
BS 3970:PART 5:1968	STERILIZING AND DISINFECTING EQUIPMENT FOR MEDICAL PRODUCTS. ELECTRICALLY HEATED STEAM GENERATORS FOR USE WITH HOSPITAL STERILIZERS
BS 7720:1995	NON-BIOLOGICAL STERILISATION INDICATORS EQUIVALENT TO THE BOWIE AND DICK TEST.
BS 7893:1997	PRESSURE-SENSITIVE ADHESIVE, CLOSING AND SEALING TAPES FOR USE WITH STERILIZATION PACKING MATERIALS
BS EN ISO 10993-7:1996	BIOLOGICAL EVALUATION OF MEDICAL DEVICES. ETHYLENE OXIDE STERILIZATION RESIDUALS
BS EN ISO 11737-2:2000	STERILIZATION OF MEDICAL DEVICES. MICROBIOLOGICAL METHODS. TESTS OF STERILITY PERFORMED IN THE VALIDATION OF A STERILIZATION PROCESS
BS EN ISO 14160:1998	STERILIZATION OF SINGLE-USE MEDICAL DEVICES INCORPORATING MATERIALS OF ANIMAL ORIGIN. VALIDATION AND ROUTINE CONTROL OF STERILIZATION BY LIQUID CHEMICAL STERILANTS
BS EN ISO 14161:2001	STERILIZATION OF HEALTH CARE PRODUCTS. BIOLOGICAL INDICATORS. GUIDANCE FOR THE SELECTION, USE AND INTERPRETATION OF RESULTS
BS EN ISO 14937:2001	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
BS EN 550:1994	STERILIZATION OF MEDICAL DEVICES. VALIDATION AND ROUTINE CONTROL OF ETHYLENE OXIDE STERILIZATION
BS EN 556-1:2001	STERILIZATION OF MEDICAL DEVICES. REQUIREMENTS FOR MEDICAL DEVICES TO BE DESIGNATED "STERILE". REQUIREMENTS FOR TERMINALLY STERILIZED MEDICAL DEVICES
BS EN 868-1:1997	PACKAGING MATERIALS AND SYSTEMS FOR MEDICAL DEVICES WHICH ARE TO BE STERILIZED. GENERAL REQUIREMENTS AND TEST METHODS
BS EN 1041:1998	INFORMATION SUPPLIED BY THE MANUFACTURER WITH MEDICAL DEVICES
BS EN 1174-1:1996	STERILIZATION OF MEDICAL DEVICES. ESTIMATION OF THE POPULATION OF MICRO-ORGANISMS ON PRODUCT. REQUIREMENTS

BS EN 1174-2:1997	STERILIZATION OF MEDICAL DEVICES. ESTIMATION OF THE POPULATION OF MICRO-ORGANISMS ON PRODUCT. GUIDANCE
BS EN 1174-3:1997	STERILIZATION OF MEDICAL DEVICES. ESTIMATION OF THE POPULATION OF MICRO-ORGANISMS ON PRODUCT. GUIDE TO THE METHODS FOR VALIDATION OF MICROBIOLOGICAL TECHNIQUES
BS EN 1642:1997	DENTISTRY. MEDICAL DEVICES FOR DENTISTRY. DENTAL IMPLANTS
00/560097 DC	BS EN 13824. STERILIZATION OF MEDICAL DEVICES. VALIDATION AND ROUTINE CONTROL OF ASEPTIC PROCESSES. REQUIREMENTS AND GUIDANCE
02/560165 DC	BS EN 556-2. STERILIZATION OF MEDICAL DEVICES. REQUIREMENTS FOR MEDICAL DEVICES TO BE DESIGNATED "STERILE". PART 2. REQUIREMENTS FOR ASEPTICALLY PROCESSED MEDICAL DEVICES
02/563832 DC	BS EN 1641. DENTISTRY. MEDICAL DEVICES FOR DENTISTRY. MATERIALS
02/563845 DC	BS EN 1642. DENTISTRY. MEDICAL DEVICES FOR DENTISTRY. DENTAL IMPLANTS

APPENDIX C

EUROPEAN STANDARDS:

EUROPEAN STANDARD BODIES	STANDARD REFERENCE	TITLES	RATIFICATION DATE	PUBLICATION DATE
CEN	EN 285	STERILIZATION - STEAM STERILIZERS - LARGE STERILIZERS	1996	C181 OF 1999-06-26
CEN	EN 550	STERILIZATION OF MEDICAL DEVICES - VALIDATION AND ROUTINE CONTROL OF ETHYLENE OXIDE STERILISATION	1994	C 181 OF 1999-06-26
CEN	EN 552	STERILIZATION OF MEDICAL DEVICES - VALIDATION AND ROUTINE CONTROL OF STERILISATION BY IRRADIATION	1994	C 181 OF 1999-06-26
CEN	EN 552 A1	STERILIZATION OF MEDICAL DEVICES - VALIDATION AND ROUTINE CONTROL OF STERILISATION BY IRRADIATION	1994 1999	C 288 OF1999-10-09
CEN	EN 552:1994/ A2-.2000	STERILISATION OF MEDICAL DEVICES - VALIDATION AND ROUTINE CONTROL OF STERILISATION BY IRRADIATION		C 182 OF 2002-07-31
CEN	EN 554	STERILIZATION OF MEDICAL DEVICES - VALIDATION AND ROUTINE CONTROL OF STERILISATION BY MOIST HEAT	1994	C181 OF 1999-06-26
CEN	EN 556	STERILIZATION OF MEDICAL DEVICES - REQUIREMENTS FOR MEDICAL DEVICES TO BE LABELLED STERILE	1994	C181 OF 1999-06-26
CEN	EN 556-1:2001	STERILISATION OF MEDICAL DEVICES - REQUIREMENTS FOR MEDICAL DEVICES TO BE DESIGNATED 'STERILE' - PART 1:REQUIREMENTS FOR TERMINALLY STERILISED MEDICAL DEVICES		C 182 OF 2002-07-31
CEN	EN 866	BIOLOGICAL SYSTEMS FOR TESTING STERILIZERS	1997A	
CEN	EN 867	NON-BIOLOGIACL SYSTEMS FOR USE IN STERILIZERS	1997B	
CEN	EN 868-1	PACKAGING MATERIALS AND SYSTEMS FOR MEDICAL DEVICES WHICH ARE TO BE STERILIZED - PART 1 : GENERAL REQUIREMENTS AND TEST METHODS PART 2 - PART 5	1997	C 181 OF 1999-06-26
CEN	EN 1174-2	STERILIZATION OF MEDICAL DEVICES - ESTIMATION OF THE POPULATION OF MICRO-ORGANISMS ON PRODUCT – PART 2: GUIDANCE	1996	C181 OF 1999-06-26
CEN	EN 1174-3	STERILIZATION OF MEDICAL DEVICES - ESTIMATION OF THE POPULATION OF MICRO-ORGANISMS ON PRODUCT – PART 3: GUIDE TO THE METHODS FOR VALIDATION OF MICROBIOLOGICAL TECHNIQUES	1996	C 181 OF 1999-06-26

CEN	EN 1422	STERILISERS FOR MEDICAL PURPOSES - ETHYLENE OXIDE STERILISERS - REQUIREMENTS AND TEST METHODS	1997	C181 OF 1999-06-26
CEN	EN 1441 (SUPERSEDED)	MEDICAL DEVICES - RISK ANALYSIS	1997	C181 OF 1999-06-26
CEN	EN 1639	DENTISTRY - MEDICAL DEVICES FOR DENTISTRY - INSTRUMENTS	1996	C 181 OF 1999-06-26
CEN	EN 1640	DENTISTRY - EQUIPMENT	1996	C 181 OF 1999-06-26
CEN	EN 1641	DENTISTRY - MEDICAL DEVICES FOR DENTISTRY - MATERIALS	1996	C181 OF 1999-06-26
CEN	EN 1642	DENTISTRY - MEDICAL DEVICES FOR DENTISTRY - DENTAL IMPLANTS	1996	C181 OF 1999-06-26
	ISO 13683	STERILIZATION OF HEALTH CARE PRODUCTS- REQUIREMENTS FOR VALIDATION AND ROUTINE CONTROL OF MOIST HEAT STERILIZATION IN HEALTH CARE FACILITIES.	1997	
	93/42/EEC	OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES. No L169	1993	
CEN	EN 13060	SMALL STEAM STERILIZERS	2004	2004

Relevant web site:
http://europa.eu.int/comm/enterprise/newapproach/standization/harmstds/reflist/meddev.i

APPENDIX D

FURTHER USEFUL REFERENCES AND GUIDELINES FOR DECONTAMINATION/STERILISATION PROCESSES:

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