NSAI Standards

Irish Standard
I.S. EN ISO 20857:2013

Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 20857:2010)

I.S. EN ISO 20857:2013

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Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20857

April 2013

ICS 11.080.01

English Version

Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 20857:2010)

Stérilisation des produits de santé - Chaleur sèche - Exigences pour l'élaboration, la validation et le contrôle de routine d'un processus de stérilisation pour dispositifs médicaux (ISO 20857:2010)

Sterilisation von Produkten für die Gesundheitsfürsorge - Trockene Hitze - Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung von industriellen Sterilisationsverfahren für Medizinprodukte (ISO 20857:2010)

This European Standard was approved by CEN on 5 April 2013.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of ISO 20857:2010 has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 20857:2013 by Technical Committee CEN/TC 204 “Sterilization of medical devices” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2013, and conflicting national standards shall be withdrawn at the latest by October 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives.

For relationship with EU Directives, see informative Annex ZA, B and C, which are integral parts of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 20857:2010 has been approved by CEN as EN ISO 20857:2013 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 90/385/EEC on active implantable medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 90/385/EEC

Clauses of this EN	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/Notes
4,5,6,7,8,9,10,11,12	7	This relevant Essential Requirement is only partly addressed in this European Standard. Packaging for maintenance of sterility during transportation and storage are not covered

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Standard.

Annex ZB
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZB.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clauses of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4,5,6,7,8,9,10,11,12	8.3	This relevant Essential Requirement is only partly addressed in this European Standard. Packaging for maintenance of sterility during transportation and storage are not covered
4,5,6,7,8,9,10,11,12	8.4	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Standard.

Annex ZC
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on *in vitro* diagnostic medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 98/79/EC on *in vitro* diagnostic medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZC.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZC.1 — Correspondence between this European Standard and Directive 98/79/EC

Clauses of this EN	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/Notes
4,5,6,7,8,9,10,11,12	B.2.3	This relevant Essential Requirement is only partly addressed in this European Standard. Packaging for maintenance of sterility during transportation and storage are not covered
4,5,6,7,8,9,10,11,12	B.2.4	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this Standard.

I.S. EN ISO 20857:2013

INTERNATIONAL STANDARD

ISO 20857

First edition
2010-08-15

Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices

Stérilisation des produits de santé — Chaleur sèche — Exigences pour l'élaboration, la validation et le contrôle de routine d'un processus de stérilisation pour dispositifs médicaux

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 20857 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

Introduction

A sterile medical device is one that is free of viable microorganisms. International Standards that specify requirements for development, validation and routine control of sterilization processes, require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; inevitably this means that there is always a finite probability that a microorganism may survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one product in a population subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a product.

This International Standard describes requirements that, if met, will provide a dry heat sterilization process capable of sterilizing medical devices through appropriate microbicidal activity. This International Standard also describes requirements that, if met, will provide a dry heat depyrogenation process through an appropriate denaturation activity. Furthermore, such compliance permits prediction, with reasonable confidence, that there is a low probability of there being a viable microorganism present on the product after processing. Specification of this probability is a matter for regulatory authorities and may vary from country to country (see for example EN 556-1 and ANSI/AAMI ST67). Additionally, there will be a low probability of pyrogenic material of bacterial origin being present on the product after the application of a depyrogenation process.

Generic requirements of the quality management systems for design/development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production in ISO 13485. The standards for quality management systems recognise that, for certain processes used in manufacturing or reprocessing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization and depyrogenation are examples of such processes. For this reason, sterilization and depyrogenation processes are validated for use, the performance of the processes is monitored routinely, and the equipment is maintained.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of factors including:

a) the microbiological status of incoming raw materials and/or components;

b) the validation and routine control of any cleaning and disinfection procedures used on the product;

c) the control of the environment in which the product is manufactured, assembled and packaged;

d) the control of equipment and processes;

e) the control of personnel and their hygiene;

f) the manner and materials in which the product is packaged;

g) the conditions under which product is stored.

These factors also need consideration for the provision of reliable assurance of depyrogenation.

The type of contamination on the product to be sterilized varies and this variation influences the effectiveness of a sterilization and depyrogenation process. Product that has been used in a health care setting and is being presented for resterilization in accordance with the manufacturer's instructions (see ISO 17664) should be regarded as a special case. There is potential for such product to possess a wide range of contaminating microorganisms and residual inorganic and/or organic contamination in spite of the application of a cleaning process. Hence, particular attention has to be given to the validation and control of the cleaning and disinfection processes used during reprocessing.

The requirements are the normative parts of this International Standard with which compliance is claimed. The guidance given in the informative annexes is not normative and is not provided as a check list for auditors. The guidance provides explanations as well as methods that are accepted as being suitable means for complying with the requirements. Approaches other than those given in the guidance may be used if they are effective in achieving compliance with the requirements of this International Standard.

The development, validation and routine control of a sterilization process and/or a depyrogenation process comprise a number of discrete but interrelated activities, for example calibration, maintenance, product definition, process definition, installation qualification, operational qualification and performance qualification. While the activities required by this International Standard have been grouped together and are presented in a particular order, this International Standard does not require that the activities be performed in the order that they are presented. The activities required are not necessarily sequential, as the programmes of development and validation might be iterative. It is possible that performing these different activities will involve a number of separate individuals and/or organizations, each of whom undertake one or more of these activities. This International Standard does not specify the particular individuals or organizations to carry out the activities.

Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices

1 Scope

1.1 Inclusions

1.1.1 This International Standard specifies requirements for the development, validation and routine control of a dry heat sterilization process for medical devices.

NOTE Although the scope of this International Standard is limited to medical devices, it specifies requirements and provides guidance that might be applicable to other health care products.

1.1.2 Although this International Standard primarily addresses dry heat sterilization, it also specifies requirements and provides guidance in relation to depyrogenation processes using dry heat.

NOTE Dry heat is often used for the depyrogenation of equipment, components and health care products and its effectiveness has been demonstrated. The process parameters for sterilization and/or depyrogenation are time and temperature. Because the conditions for depyrogenation are typically more severe than those required for sterilization, a process that has been validated for product depyrogenation will result in product sterility without additional validation.

1.2 Exclusions

1.2.1 This International Standard does not specify requirements for the development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease.

NOTE See also ISO 22442-1, ISO 22442-2 and ISO 22442-3.

1.2.2 This International Standard does not apply to processes that use infrared or microwaves as the heating technique.

1.2.3 This International Standard does not detail a specified requirement for designating a medical device as "sterile."

NOTE Attention is drawn to national or regional requirements for designating medical devices as “sterile.” See, for example, EN 556-1 or ANSI/AAMI ST67.

1.2.4 This International Standard does not specify a quality management system for the control of all stages of production of medical devices.

NOTE It is not a requirement of this International Standard to have a complete quality management system during manufacture, but the elements of a quality management system that are the minimum necessary to control the sterilization process are normatively referenced at appropriate places in the text (see, in particular, Clause 4). Attention is drawn to the standards for quality management systems (see ISO 13485) that control all stages of production of medical devices, including the sterilization process. Regional and national regulations for the provision of medical devices might require implementation of a complete quality management system and the assessment of that system by a third party.

1.2.5 This International Standard does not specify requirements for occupational safety associated with the design and operation of dry heat sterilization and/or depyrogenation facilities.