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| **SN** | **TITLE** | **SCOPE** |
| 1 | CDC21(476)DTZS/ISO 7199:2016   Cardiovascular implants and artificial organs - Blood-Gas exchangers (Oxygenators). | This document specifies requirements for sterile, single-use, extracorporeal blood-gas exchangers (oxygenators) intended for supply of oxygen to, and removal of carbon dioxide from, the blood of humans. This document also applies to heat exchangers and arterial filters that are integral parts of the oxygenator. This document also applies to external equipment unique to the use of the oxygenator. This document does not apply to— implanted oxygenators,— liquid oxygenators,— extracorporeal circuits (blood tubing),— separate heat exchangers,— separate ancillary devices, and— separate arterial line filter.. |
| 2 | CDC 21 (474) DTZS/ISO 11135:2014 Sterilization of Healthcare Products-Ethylene Oxide-Part 1: Requirements, Validation and routine control of a sterilization process for medical devices. | * 1. Inclusions

This International Standard specifies requirements for the development, validation and routine control of an ethylene oxide sterilization process for medical devices in both the industrial and health care facility settings, and it acknowledges the similarities and differences between the two applications. NOTE 1 Among the similarities are the common need for quality systems, staff training, and proper safety measures. The major differences relate to the unique physical and organizational conditions in health care facilities, and to the initial condition of reusable medical devices being presented for sterilization. NOTE 2 Health care facilities differ from medical device manufacturers in the physical design of processing areas, in the equipment used, and in the availability of personnel with adequate levels of training and experience. The primary function of the health care facility is to provide patient care; medical device reprocessing is just one of a myriad of activities that are performed to support that function. NOTE 3 In terms of the initial condition of medical devices, medical device manufacturers generally sterilize large numbers of similar medical devices that have been produced from virgin material. Health care facilities, on the other hand, must handle and process both new medical devices and reusable medical devices of different descriptions and with varying levels of bioburden. They are therefore faced with the additional challenges of cleaning, evaluating, preparing and packaging a medical device prior to sterilization. In this International Standard, alternative approaches and guidance specific to health care facilities are identified as such. NOTE 4 EO gas and its mixtures are effective sterilants that are primarily used for heat- and/or moisture-sensitive medical devices that cannot be moist heat sterilized. NOTE 5 Although the scope of this International Standard is limited to medical devices, it specifies requirements and provides guidance that can be applicable to other health care products.1.2 Exclusions1.2.1 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. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.NOTE See ISO 22442-1, ISO 22442-2 and ISO 22442-3.1.2.2 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 ST67.1.2.3 This International Standard does not specify a quality management system for the control of all stages of production of medical devices. INTERNATIONAL STANDARD ISO 11135:2014(EISO 11135:2014(E)NOTE The effective implementation of defined and documented procedures is necessary for the development, validation and routine control of a sterilization process for medical devices. Such procedures are commonly considered to be elements of a quality management system. It is not a requirement of this International Standard to have a full quality management system during manufacture or reprocessing. The necessary elements 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 or reprocessing of medical devices. National and/or regional regulations for the provision of medical devices might require the implementation of a full quality management system and the assessment of that system by a third party.1.2.4 This International Standard does not specify requirements for occupational safety associated with the design and operation of EO sterilization facilities.NOTE 1 For further information on safety, see examples in the Bibliography. National or regional regulations may also exist.NOTE 2 EO is toxic, flammable and explosive. Attention is drawn to the possible existence in some countries of regulations giving safety requirements for handling EO and for premises in which it is used.1.2.5 This International Standard does not cover sterilization by injecting EO or mixtures containing EO directly into packages or a flexible chamber.NOTE See ISO 14937 for these types of EO processes.1.2.6 This International Standard does not cover analytical methods for determining levels of residual EO and/or its reaction products.NOTE 1 For further information see ISO 10993-7. NOTE 2 Attention is drawn to the possible existence of national or regional regulations specifying limits for the level of EO residues present on or in medical devices. |
| 3 | CDC 21 (477) DTZS/ISO 14708-1:2014 Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer. | This part of ISO 14708 specifies requirements that are generally applicable to active implantable medical devices.NOTE 1 For particular types of active implantable medical devices, these general requirements are supplemented or modified by the requirements of particular parts of ISO 14708.The tests that are specified in ISO 14708 are type tests and are to be carried out on samples of an active implantable medical device to show compliance. This part of ISO 14708 is applicable not only to active implantable medical devices that are electrically powered but also to those powered by other energy sources (for example by gas pressure or by springs).This part of ISO 14708 is also applicable to some non-implantable parts and accessories of the active implantable medical devices.NOTE 2 The device that is commonly referred to as an active implantable medical device can be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.NOTE 3 In this part of ISO 14708, terms printed in small capital letters are used as defined in Clause 3 . Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.NOTE 4 The terminology used in this part of ISO 14708 is intended to be consistent with the terminology of ISO/TR 14283:2004. |
| 4 | CDC 21 (478) DTZS/ISO 14708-2:2019 Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers. | This document specifies requirements that are applicable to those active implantable medical devices intended to treat bradyarrhythmias and devices that provide therapies for cardiac resynchronization. The tests that are specified in this document are type tests, and are to be carried out on samples of a device to show compliance. This document was designed for bradyarrhythmia pulse generators used with endocardial leadsor epicardialleads. At the time of this edition, the authors recognized the emergence of leadless technologies for which adaptations of this part will be required. Such adaptations are left to the discretion of manufacturers incorporating these technologies.This document is also applicable to some non-implantable parts and accessories of the devices (see Note 1). The electrical characteristics of the implantable pulse generator or lead are determined either by the appropriate method detailed in this particular standard or by any other method demonstrated to have an accuracy equal to, or better than, the method specified. In case of dispute, the method detailed in this particular standard applies. Any features of an active implantable medical device intended to treat tachyarrhythmias are covered by ISO 14708-6.NOTE 1 The device that is commonly referred to as an active implantable medical device can in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device. NOTE 2 In this document, terms printed in italics are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in italics unless the concept thus qualified is also defined |