|  |  |  |
| --- | --- | --- |
| **SN** | **TITLE** | **SCOPE** |
| 1 | CDC 21 (938) DTZS/ISO 5832-9:2019 Implants for surgery-Metallic materials-Part 9: Wrought high Nitrogen stainless steel | This document specifies the characteristics of, and corresponding test methods for, wrought stainless steel containing a mass fraction of 0.25 % to 0.50 % nitrogen for use in the manufacture of surgical implants for which high levels of strength and corrosion resistance are required.  NOTE 1 The mechanical properties of a sample obtained from a finished product made of this alloy can differ from those specified in this document.  NOTE 2 Requirements for other stainless steels for implants for surgery can be found in ISO 5832-1. |
| 2 | CDC 21 (927) DTZS/ISO 5832-11:2014 Implants for surgery-Metallic materials-Part 11: Wrought Titanium 6-Aluminium 7-Niobium alloy | This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 7-niobium alloy (Ti-6-Al 7-Nb) for use in the manufacture of surgical implants.  NOTE The mechanical properties of a sample obtained from a finished product made of this alloy might not necessarily comply with those specified in this part of ISO 5832. |
| 3 | CDC 21 (928) DTZS/ISO 5832-12:2019 Implants for surgery-Metallic materials-Part 12: Wrought-Cobalt-Chromium-Molybdenum alloy | This document specifies the requirements for two wrought cobalt 28-chromium 6-molybdenum alloys used for surgical implants. The properties apply specifically to wrought bar, rod and wire.  NOTE 1 The mechanical properties of a sample obtained from a finished product made of this alloy can differ from those specified in this document.  NOTE 2 The high carbon content of this alloy produces a structure containing a significant carbide distribution. This can be adjusted either in the production of the bar or in subsequent thermomechanical processing to produce the final device. Carbide distribution in the final device is not included as part of this document. |
| 4 | CDC 21 (929) DTZS/ISO 5832-14:2019 Implants for surgery-Metallic materials-Part 14: Wrought Titanium 15-Molybdenum 5-Zirconium 3-Aluminium alloy | This document specifies the characteristics of, and corresponding test methods for, the wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy for use in the manufacture of surgical implants. This document applies to materials in bar form up to a maximum diameter of 100 mm.  NOTE The mechanical properties of a sample obtained from a finished product made of this alloy can differ from those specified in this document |
| 5 | CDC 21 (932) DTZS/ISO 6892-1: 2019 Metallic materials-Tensile testing-Part 1: Method of test at room temperature | This document specifies the method for tensile testing of metallic materials and defines the mechanical properties which can be determined at room temperature.  NOTE Annex A contains further recommendations for computer controlled testing machines |
| 6 | CDC 21 (941) DTZS/ISO11607-1:2019 Packaging for terminally sterilized medical devices-Part 1: Requirements for materials, sterile barrier systems and packaging systems | This document specifies requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use. It is applicable to industry, to health care facilities, and to wherever medical devices are placed in sterile barrier systems and sterilized. It does not cover all requirements for sterile barrier systems and packaging systems for medical devices that are manufactured aseptically. Additional requirements can be necessary for drug/device combinations. It does not describe a quality assurance system for control of all stages of manufacture. It does not apply to packaging materials and/or systems used to contain a contaminated medical device during transportation of the item to the site of reprocessing or disposal. |
| 7 | CDC 21 (936) DTZS/ ISO14155:2020 Clinical investigation of medical devices for human subjects - Good clinical practice | This document addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical devices. For post-market clinical investigations, the principles set forth in this document are intended to be followed as far as relevant, considering the nature of the clinical investigation (see Annex I). This document specifies general requirements intended to — protect the rights, safety and well-being of human subjects, — ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results, — define the responsibilities of the sponsor and principal investigator, and — assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.  NOTE 1 Users of this document need to consider whether other standards and/or national requirements also apply to the investigational device(s) under consideration or the clinical investigation. If differences in requirements exist, the most stringent apply.  NOTE 2 For Software as a Medical Device (SaMD) demonstration of the analytical validity (the SaMD’s output is accurate for a given input), and where appropriate, the scientific validity (the SaMD’s output is associated to the intended clinical condition/physiological state), and clinical performance (the SaMD’s output yields a clinically meaningful association to the target use) of the SaMD, the requirements of this document apply as far as relevant (see Reference [4]). Justifications for exemptions from this document can consider the uniqueness of indirect contact between subjects and the SaMD.  This document does not apply to in vitro diagnostic medical devices. However, there can be situations, dependent on the device and national or regional requirements, where users of this document might consider whether specific sections and/or requirements of this document could be applicable |
| 8 | CDC 21 (939) DTZS / ISO14630:2012 Non-active surgical implants-General requirements | This International Standard specifies general requirements for non-active surgical implants, hereafter referred to as implants. This International Standard is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants, intra-ocular lenses and implants utilizing viable animal tissue. With regard to safety, this International Standard specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate compliance with these requirements. Additional tests are given or referred to in level 2 and level 3 standards.  NOTE This International Standard does not require that the manufacturer have a quality management system in place. However, the application of a quality management system, such as that described in ISO 13485, might be appropriate to help ensure that the implant achieves its intended performance |
| 9 | CDC 21 (930) DTZS/ISO14971:2019 Medical devices-Application of risk management to medical devices | This document specifies terminology, principles and a process for risk management of medical devices, including software as a medical device and in vitro diagnostic medical devices. The process described in this document intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements of this document are applicable to all phases of the life cycle of a medical device. The process described in this document applies to risks associated with a medical device, such as risks related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability. The process described in this document can also be applied to products that are not necessarily medical devices in some jurisdictions and can also be used by others involved in the medical device life cycle. This document does not apply to: — decisions on the use of a medical device in the context of any particular clinical procedure; or — business risk management. This document requires manufacturers to establish objective criteria for risk acceptability but does not specify acceptable risk levels. Risk management can be an integral part of a quality management system. However, this document does not require the manufacturer to have a quality management system in place.  NOTE Guidance on the application of this document can be found in ISO/TR 24971[9] |
| 10 | CDC 21 (934) DTZS/ ISO15675:2016 Cardiovascular implants and artificial organs-Cardiopulmonary bypass systems - Arterial blood line filter | This document specifies requirements for sterile, single-use, arterial blood line filters intended to filter and remove emboli, debris, blood clots and other potentially hazardous solid and gaseous material from the blood of humans during cardiopulmonary bypass surgery |