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| **SN** | **TITLE** | **SCOPE** |
| 1 | **CDC 21(469) DTZS/ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification of degradation products from polymeric medical devices.** | This part of ISO 10993 provides general requirements for the design of tests in a simulated environment for identifying and quantifying degradation products from finished polymeric medical devices ready for clinical use. This part of ISO 10993 describes two test methods to generate degradation products, an accelerated degradation test as a screening method and a real-time degradation test in a simulated environment. For materials that are intended to polymerize in situ, the set or cured polymer is used for testing. The data generated are used in the biological evaluation of the polymer. This part of ISO 10993 considers only non-resorbable polymers. Similar but appropriately modified procedures may be applicable for resorbable polymers. This part of ISO 10993 considers only those degradation products generated by a chemical alteration of the finished polymeric device. It is not applicable to degradation of the device induced during its intended use by mechanical stress, wear or electromagnetic radiation or biological factors such as enzymes, other proteins and cellular activity. NOTE An informative text discussing environmental stress cracking (ESC) of polymers is included as a potential aid to the design of degradation studies (see Annex B). The biological activity of the debris and soluble degradation products is not addressed in this part of ISO 10993, but should be evaluated according to the principles of ISO 10993-1, ISO 10993-16 and ISO 10993-17. Because of the wide range of polymeric materials used in medical devices, no specific analytical techniques are identified or given preference. No specific requirements for acceptable levels of degradation products are provided in this part of ISO 10993. |
| 2 | **CDC 21(465) DTZS/ISO 10993-7:2008 Biological evaluation of medical Devices-Part 7: Ethylene oxide sterilization residuals.** | This part of ISO 10993 specifies allowable limits for residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) in individual EO-sterilized medical devices, procedures for the measurement of EO and ECH, and methods for determining compliance so that devices may be released. Additional background, including guidance and a flowchart showing how this document is applied, are also included in the informative annexes. EO-sterilized devices that have no patient contact (e.g., in vitro diagnostic devices) are not covered by this part of ISO 10993. NOTE This part of ISO 10993 does not specify limits for ethylene glycol (EG). |
| 3 | **CDC 21(472) DTZS/ISO 7886-3:2020 Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed dose immunization (Revision of TZS 993-3:2007).** | This document specifies the properties and performance of sterile single-use hypodermic syringes with an auto-disable syringe feature intended to deliver a fixed dose of vaccine immediately after filling. The syringes can be made of plastic, rubber or other materials and can be with or without needle and needle protection feature. This document does not specify the design of the auto-disable syringe feature. This document is not applicable to syringes for use with insulin (covered by ISO 8537), syringes for use with power-driven syringe pumps (covered by ISO 7886-2), reuse prevention syringes (covered by ISO 7886-4) or syringes designed to be prefilled (covered by the ISO 11040 series). It does not address compatibility with injection fluids/vaccines. |