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Parts 1 & 3 of ISO 10993-1 as revised in July 2004. - This is an important "public domain" safety document and for the safety of health care workers is must be read and understood. A U.S. Food and Drug Administration (FDA) approved English translation of this manual was available in the. ISO 10993-1:2015(E). ISO 10993-3:2009(E). ISO 10993-2:2017. The use of medical devices – Evaluation and documentation for medical devices. ISO 10993-2. is ISO 10993-1 applicable in the United States and abroad. ISO 10993-2:2018(E). Corrections ISO 10993-2:2017. . + Instructions for Use ISO 10993-3:2015(E). is a version of ISO 10993:2007 that adds to Part 1 and Part 3. + References + Changes ISO 10993-2:2017 + Briefs . + Background ISO 10993-2:2007 WG 3, Biological evaluation of medical devices + Preamble: + In several regions of the world, a number of biological and toxicological requirements must be met when considering the sale and use of medical devices, including surgical, diagnostic, orthopedic, cosmetic, ophthalmic, dental, and physiological implants. The goal of these requirements is to promote safety by: • requiring that the risk be identified by the producer and documented before sale • enforcing the disposal of the device after use ISO 10993-3:2017(E). ISO 10993-4:2009 + Medical device manufacturers must be familiar with the information presented in Part 1 of this specification, as well as with those in Part 3, which address the biological and toxicological properties of medical devices. + Scope ISO 10993-1 does not cover the criteria for evaluation of newly developed devices that are not yet on the market, such as preclinical and developmental studies, or investigational devices. + 1. Scope ISO 10993-1:2018(E). Part 1: Tests for biological evaluation of medical devices, testing methods, and test guidelines ISO 10993-1 is concerned with the development of medical devices, including medical devices for in vitro use and medical devices for in vivo use. In vitro uses refer to those tests or assessments 2d92ce491b