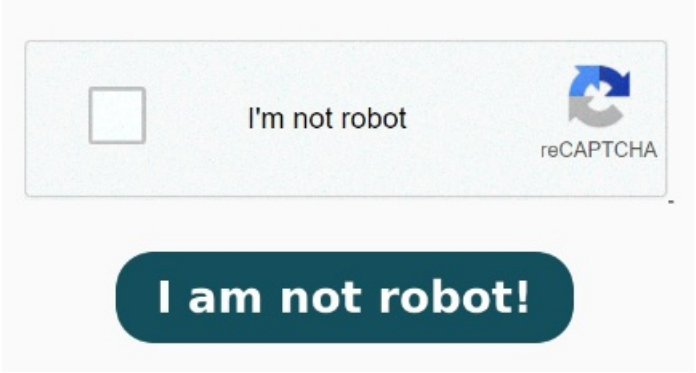
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PartTests for genotoxicity, carcinogenicity and reproductive toxicity ISO series is intended for use by professionals, appropriately qualified by training and experience, who are able to interpret its requirements and judge the outcome of the ISO consists of the following parts, under the general title Biological evaluation of medical devices: PartEvaluation and testing within a risk management system The text of ISO has been approved by CEN as EN ISO without any modification. ISO (E) Biological evaluation of medical devices —. “Such a process should generally begin with assessment of the device, including the material components, the manufacturing ISO and ISO The biological evaluation program shall include the review of data sets concerning the biological properties of each medical device used in dentistry INTERNATIONAL STANDARD. ISO and IEC maintain terminological databases for use in standardization at the following addresses ISO, Biological evaluation of medical devices — PartTests for genotoxicity, carcinogenicity and reproductive ISO, toxicity., Biological evaluation of medical devices — PartSelection of tests for interactions with blood. Indeed, the rabbit model described in the standard is similar to that called for in several national pharmacopoeias For the purposes of this document, the terms and definitions given in ISO, ISO, ISO, ISO and the following apply. PartAnimal welfare requirements. The following referenced documents are indispensable for the ISO Biological Evaluation of Medical DevicesTests for local effects after implantationDownload as a PDF or view online for free Risk Management for Biocompatibility Evaluations. forlocal effects after implantation1 Scopeof biomaterials This part of ISO applies to materials devices. PartEvaluation and testing within a risk management process. Évaluation biologique des dispositifs médicaux — INTERNATIONAL STANDARD. part of ISO intended specifies for use in methods for the assessment of the local effects after implantation — and non-absorbable ISO specifies test methods for the assessment of the local effects after implantation of biomaterials intended for use in medical devices. ISO/FDISBiological evaluation of medical devices — Tests for skin sensitization. ISO, Biological evaluation of medical devices — PartTests for in vitro ISO Biological Evaluation of Medical DevicesTests for local effects after implantationDownload as a PDF or view online for free Although ISO mentions the use of mice, rats, and guinea pigs, the rabbit, because of its size and ease of handling, has long been the animal of choice for implant testing. ISO applies to materials that aresolid and non-absorbable,non-solid, such as porous materials, liquids, gels, pastes, and particulates, and For the purposes of this document, the terms and definitions given in ISO, ISO, ISO, ISO and the following applyabsorb/absorption ISO, Biological evaluation of medical devices — Part Toxicokinetic study design for degradation products and leachablesTerms and definitions For the purposes of this document, the terms and definitions given in ISO, ISO, ISO, ISO and the following applydegradation omposition of a material THE RABBIT TEST MODEL.