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ISO 10993-9:1999, Biological Evaluation Of Medical Devices -- Part 9: Framework For Identification And Quantification Of Potential Degradation Products



Synopsis

This part of ISO 10993 provides general principles for the systematic evaluation of the potential and observed biodegradation of medical devices and for the design and performance of biodegradation studies. This part of ISO 10993 is not applicable to viable-tissue engineered products; methodologies for the generation of degradation products by mechanical processes. Methodologies for the production of this type of degradation product are described in specific product standards, where available; leachable components which are not degradation products. Where product standards provide applicable product-specific methodologies for the identification and quantification of degradation products, those standards shall be considered as alternatives. This title may contain less than 24 pages of technical content.

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