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Synopsis

ISO 10993-1:2003 describes the general principles governing the biological evaluation of medical devices; the categorization of devices based on the nature and duration of their contact with the body; the selection of appropriate tests. It does not cover testing of materials and devices that do not come into direct or indirect contact with the patient’s body, nor does it cover biological hazards arising from any mechanical failure. Other parts of ISO 10993 cover specific tests. This title may contain less than 24 pages of technical content.

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