TANZANIA BUREAU OF STANDARDS
DIRECTORATE OF STANDARDS DEVELOPMENT
CHEMICAL SECTION
DRAFT TANZANIA STANDARDS ON MEDICAL DEVICES FOR STAKEHOLDERS COMMENTS

SN	TITLE	SCOPE
1	TBS/CDC 21(5149) P3 / ISO 10993-3:2014 Biological evaluation of medical devices-Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	This part of ISO 10993 specifies strategies for risk estimation, selection of hazard identification tests and risk management, with respect to the possibility of the following potentially irreversible biological effects arising as a result of exposure to medical devices: — genotoxicity; — carcinogenicity; — reproductive and developmental toxicity. This part of ISO 10993 is applicable when the need to evaluate a medical device for potential genotoxicity, carcinogenicity, or reproductive toxicity has been established.
2	TBS/CDC 21(5150) P3 / ISO 10993- 4:2002 Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood	This part of ISO 10993 provides general requirements for evaluating the interactions of medical devices with blood. It describes **a)** a classification of medical and dental devices that are intended for use in contact with blood, based on the intended use and duration of contact as defined in ISO 10993-1, **b)** the fundamental principles governing the evaluation of the interaction of devices with blood, **c)** the rationale for structured selection of tests according to specific categories, together with the principles and scientific basis of these tests. Detailed requirements for testing cannot be specified because of limitations in the knowledge and precision of tests for interactions of devices with blood. This part of ISO 10993 describes biological evaluation in general terms and may not necessarily provide sufficient guidance for test methods for a specific device.

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