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(5018) P3 / ISO 13485:2016 Medical Devices-Quality management systems-Requirements for regulatory purposes.	This ISO standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations. Requirements of this International Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization. The processes required by this International Standard that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes. If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to this International Standard reflect any exclusion of design and development controls. If any requirement in Clauses 6, 7 or 8 of this International Standard is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in 4.2.2.
2	TBS/CDC 21(5019) P3 / ISO 10993- 1:2009 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process.	This part of ISO 10993 describes: □ the general principles governing the biological evaluation of medical devices within a risk management process; □ the general categorization of devices based on the nature and duration of their contact with the body; □ the evaluation of existing relevant data from all sources; □ the identification of gaps in the available data set on the basis of a risk analysis; □ the identification of additional data sets necessary to analyze the biological safety of the medical device; □ the assessment of the biological safety of the medical device. This part of ISO 10993 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.

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3	TBS/CDC 21(5020) P3 / ISO 10993-2:2006 Biological evaluation of medical devices-Part 2: Animal welfare requirements.	This part of ISO 10993 is aimed at those who commission, design and perform tests or evaluate data from animal tests undertaken to assess the biocompatibility of materials intended for use in medical devices, or that of the medical devices themselves. It specifies the minimum requirements to be satisfied to ensure and demonstrate that proper provision has been made for the welfare of animals used in animal tests to assess the biocompatibility of materials used in medical devices. It also makes recommendations and offers guidance intended to facilitate future further reductions in the overall number of animals used, refinement of test methods to reduce or eliminate pain or distress in animals, and the replacement of animal tests by other scientifically valid means not requiring animal tests. It applies to tests performed on living vertebrate animals, other than man, to establish the biocompatibility of materials or medical devices. It does not apply to tests performed on invertebrate animals and other lower forms; nor (other than with respect to provisions relating to species, source, health status, and care and accommodation) does it apply to testing performed on isolated tissues and organs taken from vertebrate animals that have been euthanized.

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