CBER Standards Recognition Program for Regenerative Medicine Therapies
Standards Recognition Summary (SRS)

Recognition Number: 017 **Date of Recognition:** 12/9/2025

SDO Name/Designation: ISO 22442-1 **Year of Publication:** 2020

Title: Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management

Scope: This document applies to medical devices other than *in vitro* diagnostic medical devices manufactured utilizing materials of animal origin, which are non-viable or have been rendered non-viable. It specifies, in conjunction with ISO 14971, a procedure to identify the hazards and hazardous situations associated with such devices, to estimate and evaluate the resulting risks, to control these risks, and to monitor the effectiveness of that control. Furthermore, it outlines the decision process for the residual risk acceptability, taking into account the balance of residual risk, as defined in ISO 14971, and expected medical benefit as compared to available alternatives. This document is intended to provide requirements and guidance on risk management related to the hazards typical of medical devices manufactured utilizing animal tissues or derivatives such as:
a) contamination by bacteria, moulds or yeasts;
b) contamination by viruses;
c) contamination by agents causing transmissible spongiform encephalopathies (TSE);
d) material responsible for undesired pyrogenic, immunological or toxicological reactions.

For parasites and other unclassified pathogenic entities, similar principles can apply.
This document does not stipulate levels of acceptability which, because they are determined by a multiplicity of factors, cannot be set down in such an international standard except for some particular derivatives mentioned in Annex C. Annex C stipulates levels of TSE risk acceptability for tallow derivatives, animal charcoal, milk and milk derivatives, wool derivatives and amino acids.

This document does not specify a quality management system for the control of all stages of production of medical devices.

This document does not cover the utilization of human tissues in medical devices.
NOTE 1 It is not a requirement of this document to have a full quality management system during manufacture. However, attention is drawn to international standards for quality management systems (see ISO 13485) that control all stages of production or reprocessing of medical devices.

NOTE 2 For guidance on the application of this document, see Annex A.

Extent of Recognition: Partial Recognition

Rational for Recognition: This standard is partially recognized by CDRH. CDRH concluded that this standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies. This standard is recognized in part because Clause 4.4.2, Paragraph 4 is in conflict with section IV C. (paragraph 2, page 8) of the FDA guidance: Medical Devices Containing Materials derived from Animal Sources (Except for In Vitro Diagnostic Devices), 2019. This standard applied to tissue engineered medical products regulated in CBER.

Standards Development Organization: www.ISO.org

Please note that this standard may also be recognized under the Center for Devices and Radiological Health's (CDRH) Recognized Consensus Standards Database for Medical Device, found here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm .