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

Recognition Number: 024 **Date of Recognition:** 12/9/2025

SDO Name/Designation: ISO 2244-2 **Year of Publication:** 2020

Title: Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling

Scope: This document specifies requirements for controls on the sourcing, collection, and handling (which includes storage and transport) of animals and tissues for the manufacture of medical devices utilizing materials of animal origin other than *in vitro* diagnostic medical devices. It applies where required by the risk management process as described in ISO 22442-1.

NOTE Selective sourcing is especially important for transmissible spongiform encephalopathy (TSE) risk management, i.e. when utilising animal tissue and/or their derivative originating from bovine, ovine and caprine species, deer, elk, mink or cats.

This document does not cover the utilization of human tissues in medical devices.

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

Extent of Recognition: Complete Recognition

Rational for Recognition: This standard is applicable to regenerative medicine products and does not conflict with FDA policy or guidance.

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 .