CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 038 **Date of Recognition:** 05/21/2023

SDO Name/Designation: ASTM F2150 **Year of Publication:** 2019

Title: Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Regenerative Medicine and Tissue-Engineered Medical Products

Scope:
1.1 This guide is a resource of currently available test methods for the characterization of the compositional and structural aspects of biomaterial scaffolds used in the development and manufacture of regenerative medicine and tissueengineered medical products (TEMPs). 1.2 The test methods contained herein guide characterization of the bulk physical, chemical, mechanical, and surface properties of a scaffold construct. Such properties may be important for the success of a TEMP, especially if the property affects cell retention, activity and organization, the delivery of bioactive agents, or the biocompatibility and bioactivity within the final product. 1.3 This guide may be used in the selection of appropriate test methods for the generation of an original equipment manufacture (OEM) specification. This guide also may be used to characterize the scaffold component of a finished medical product. 1.4 This guide is intended to be used in conjunction with appropriate characterization(s) and evaluation(s) of any raw or starting material(s) used in the fabrication of the scaffold, such as described in Guide F2027. 1.5 This guide addresses natural, synthetic, or combination scaffold materials with or without bioactive agents or biological activity. This guide does not address the characterization or release profiles of any biomolecules, cells, drugs, or bioactive agents that are used in combination with the scaffold, but may be used to address the effects on other (e.g., structural) properties as a result of such release. A determination of the suitability of a particular starting material and/or finished scaffold structure to a specific cell type and/or tissue engineering application is essential, but will require additional in vitro and/or in vivo evaluations considered to be outside the scope of this guide. 1.6 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use. 1.7 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Extent of Recognition: Complete Recognition

Rational for Recognition: The standard is relevant to tissue engineered products and has been found to be scientifically sound and technically accurate.

Standard Development Organization: https://www.astm.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