

CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 033

Date of Discussion: 12/07/2023

SDO Name/Designation: ISO 13019

Year of Publication: 2018

Title: Tissue-engineered medical products - Quantification of sulfated glycosaminoglycans (sGAG) for evaluation of chondrogenesis

Scope:

This document specifies test methods for the quantification of sulfated glycosaminoglycans (sGAG), one of the major extracellular matrix components in articular, meniscal, and elastic cartilages, and tissue engineered cartilage constructs

Extent of Recognition: Complete Recognition

Rational for Recognition: The standard is applicable to tissue engineered products.

Standard Development Organization: <https://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>