

CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition List-Number: 009

Date of Recognition: 4/17/2023

SDO Name/Designation: ISO 20688-1

Year of Publication: 2020

Title: Nucleic acid synthesis — Part 1: Requirements for the production and quality control of synthesized oligonucleotides

Scope:

This document specifies minimum requirements for the production and quality control of synthesized oligonucleotides (nominally up to 250 bases).

This document also describes general quality attributes for synthesized oligonucleotides as well as common methods for evaluating quality attributes.

Extent of Recognition: Complete Recognition

Rational for Recognition: This standard is relevant to regenerative medicine therapies and is recognized because it is scientifically and technically valid and does not conflict with existing regulations and policies.

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>.