

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

Recognition Number: 052

Date of Recognition: 12/8/2025

SDO Name/Designation: ISO 8392

Year of Publication: 2023

Title: Genomics informatics — Description rules for genomic data for genetic detection products and services

Scope: This document specifies requirements on the category definition and quality assessment of genomic data, including the content structure, attribute and description rules of data format, and the compilation rules of data format.

This document applies to all the genomic data used for human genetic detection products and services.

This document applies to genomic data processing and analysis, and to the quality evaluation/assessment of genomic data.

Extent of Recognition: Complete Recognition

Rational for Recognition: This standard applies to regenerative medicine therapies and does not conflict with FDA regulations and policy.

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> .