SLOVENSKI STANDARD
oSIST prEN ISO 20387:2025

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Biotehnologija - Biobančništvo - Splošne zahteve za biobančništvo (ISO/DIS 20387:2025)

Biotechnology - Biobanking - General requirements for biobanks (ISO/DIS 20387:2025)

Biotechnologie - Biobanking - Allgemeine Anforderungen an Biobanken (ISO/DIS 20387:2025)

Biotechnologie - Mise en banque de matériel biologique - Exigences générales relatives pour les biobanques (ISO/DIS 20387:2025)

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ICS:

07.080 Biologija. Botanika. Zoologija Biology. Botany. Zoology

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Biotechnology — Biobanking — General requirements for biobanks

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*.

This second edition cancels and replaces the first edition (ISO 20387:2018), which has been technically revised.

The main changes are as follows:

— update and clarification of terminology;

— addition of 4.1.10 regarding climate change;

— addition of 5.14 on collaborative activities;

— together with the addition of 5.10 and 5.11 regarding the range of performed and outsourced activities and the related conformity claim, 6.4 was updated to be more precise now about the obligatory biobanking processes;

— 6.2.2 and 6.2.3 were merged;

— 6.4 was split into 6.4 and 6.5 to separate externally provided critical processes and services from non-critical services and products;

— 7.2 and 7.3 were updated to include different cases of control over the collection, and putting acquisition and reception requirements within the same chapter as clear differentiation is not always possible;

— testing requirements were added in 7.6 and ;

— new clauses on retrieval (7.8), distribution (7.9) and disposal (7.10) were added;

— the QC clause was restructured;

— in the report requirements clause, subchapters for the preparation of the report and amendments to reports have been added;

— Clause 8 was updated based on the latest ISO requirements;

— editorial update and clarification of wording.