SLOVENSKI STANDARD
SIST EN ISO 80369-3:2016/A1:2023

01-februar-2023

Priključki z majhnim premerom za tekočine in pline za uporabo v zdravstvu - 3. del: Priključki za enteralno uporabo - Dopolnilo A1 (ISO 80369-3:2016/Amd 1:2019)

Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications - Amendment 1 (ISO 80369-3:2016/Amd 1:2019)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 3: Verbindungsstücke für enterale Anwendungen - Änderung 1 (ISO 80369-3:2016/Amd 1:2019)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 3: Raccords destinés à des applications entérales - Amendement 1 (ISO 80369-3:2016/Amd 1:2019)

Ta slovenski standard je istoveten z: **EN ISO 80369-3:2016/A1:2022**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 80369-3:2016/A1:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80369-3:2016/A1

November 2022

ICS 11.040.25

English version

Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications - Amendment 1 (ISO 80369-3:2016/Amd 1:2019)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé - Partie 3: Raccords destinés à des applications entérales - Amendement 1 (ISO 80369-3:2016/Amd 1:2019)

Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 3: Verbindungsstücke für enterale Anwendungen - Änderung 1 (ISO 80369-3:2016/Amd 1:2019)

This amendment A1 modifies the European Standard EN ISO 80369-3:2016; it was approved by CEN on 21 November 2022.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

CEN-CENELEC Management Centre:
Rue de la Science 23, B-1040 Brussels

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European foreword

The text of ISO 80369-3:2016/Amd 1:2019 has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 80369-3:2016/A1:2022 by Technical Committee CEN-CENELEC/ JTC 3 "Quality management and corresponding general aspects for medical devices" the secretariat of which is held by NEN.

This Amendment to the European Standard EN ISO 80369-3:2016 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2023, and conflicting national standards shall be withdrawn at the latest by May 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN-CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN and CENELEC websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 80369-3:2016/Amd 1:2019 has been approved by CEN-CENELEC as EN ISO 80369-3:2016/A1:2022 without any modification.

INTERNATIONAL STANDARD

ISO 80369-3

First edition
2016-07-01

AMENDMENT 1
2019-02

Small-bore connectors for liquids and gases in healthcare applications —

Part 3: Connectors for enteral applications

AMENDMENT 1

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé —

Partie 3: Raccords destinés à des applications entérales

AMENDEMENT 1

Reference number
ISO 80369-3:2016/Amd.1:2019(E)

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Published in Switzerland

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and IEC/SC 62D, *Electromedical equipment.* The draft was circulated for voting to the national bodies of both ISO and IEC.

A list of all the parts in the ISO 80369 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.