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

Part 1: General requirements

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

Partie 1: Exigences générales

FDIS stage

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for products with a health purpose including medical devices*, in collaboration with Technical Committee IEC/SC 62D, *Particular medical equipment, software, and systems,* and with the European Committee for Standardization (CEN) Technical Committee CEN/TC CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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.

This third edition cancels and replaces the second edition (ISO 80369-1:2018), which has been technically revised.

The main changes are as follows:

— update of normative references;

— update of the document according to ISO/IEC Directives, Part 2;

— for the materials used for the *small-bore connectors* the threshold of the modulus of elasticity greater than 700 MPa was introduced;

— addition of respiratory *applications*;

— addition of *interference test part*, *misconnection* and *unintended connection* definitions;

— deletion of Clause 4 for materials requirements, as those requirements are or will be placed in the individual *connector* parts of the series and normative Annex B describes the analysis and testing processes for determining *non-interconnectable* characteristics;

— revision of Annex B by summarising process description and adding figure, editorial changes and adding the dimensional analysis case “potential misconnection”;

— deletion of the original Annex C, replaced with normative reference to parts of ISO 20417;

— addition of Annex E summarizing the design assessments of the *application* parts of this series of documents;

— replacement of contents of Annex F by referencing the relevant essential principles and labelling guidance of the International Regulators Forum (IMDRF);

— extension of the use of the ISO 80369-7 *connector* to *medical devices* and *accessories* beyond intravascular and hypodermic *applications* where the *risk* is acceptable.

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

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Introduction

In the 1990s, concern grew regarding the proliferation of *medical devices* fitted with *Luer connectors* as specified in the ISO 594 series[1] and the reports of *patient* death or injury arising from *unintended connections* that resulted in the inappropriate delivery of fluids and gases via incorrect routes. In addition to clinical and workplace protocols and warnings, attention was turned to engineering solutions to reduce the probability of wrong route administration of liquids and gases.

Concerns regarding the use of *Luer connectors* with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN Bureau Technique (CEN/BT) and the European Commission. In November 1997, the newly created CEN Healthcare Forum (CHeF) steering group set up a Forum Task Group (FTG) to consider the problem.

The FTG produced CEN Report, CEN/CR 13825,[9] in which they concluded that there is a problem arising from the use of a single *connector* design to several different *applications*. In a coronary care unit, there could be as many as 40 *Luer connectors* on the *medical devices* used with a single *patient* until the use of *connectors* defined in the ISO and IEC 80369 documents started to be established. Therefore, it is not surprising that *unintended connections* were made.

Medical devices have, for many years, followed the established principle of "safety under single fault conditions." Simply stated, this means that a single fault should not result in an unacceptable *risk*. This principle is embodied in the requirements of numerous *medical device* standards.[6] Extending this principle to the use of *Luer connectors* (i.e. that an *unintended connection* should not result in an unacceptable *risk* to a *patient*) the FTG recommended that the *Luer connector* should be restricted to *medical devices* intended to be connected to the vascular system or a hypodermic syringe. In addition, the FTG recommended that new designs of *small-bore connectors* should be developed for other *applications*, and these should be *non-interconnectable* with *Luer connectors* and each other.

International medical device regulators forum (IMDRF), GRRP N47:2024,[10] Essential Principle 5.1.3, addresses this type of problem:

> Risk control measures adopted by manufacturers for the design and manufacture of the medical device and IVD medical device should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, manufacturers should control risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers should, in the following order of priority:
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> a) eliminate or appropriately reduce risks through safe design and manufacture;
>
> b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated;
>
> c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

It is understood that *small-bore connector* systems cannot be designed to overcome all chances of *unintended connections* with the potential for wrong route administration or to eliminate deliberate misuse. With these *application*-specific *connectors* now available, the *risk* of unintended connections and wrong route administration is greatly reduced thereby improving *patient* safety. Introduction of *medical devices* and *accessories* utilizing these *small-bore connectors* is progressing albeit slowly.

The *risks* associated with *unintended connections* and subsequent wrong route administration of liquids and gases cannot be fully assessed until these *small-bore connectors* are part of a *medical device* or *accessory*. Therefore, the intended *applications* specified are recommendations. It is expected that particular *medical*

device standards will reference the *connectors* from the relevant parts of the ISO and IEC 80369 series if considered appropriate.

This document contains the general requirements to reduce *connections* between *small-bore connectors* used in different *applications* as well as specifying those *applications*.

It specifies the general requirements and *test methods* for assessing the *non-interconnectable* characteristics of *small-bore connectors* within the ISO and IEC 80369 series.

The *Luer connector* as originally defined in the withdrawn ISO 594 series has been widely used on many *medical devices* and *accessories* and in a wide range of clinical *applications* for many years. The clinical *applications* that present the highest *risk* to a *patient* from wrong route administration of liquids and gases have been identified and are those included in the *application* parts of the ISO and IEC 80369 series. ISO 80369-7, which replaces the ISO 594 series (i.e. the *Luer connector*), is intended for use with intravascular or hypodermic *applications.*

However, there are currently *medical devices* and *accessories* which incorporate a *Luer connector*, but do not fall into any of the *applications* specified by the ISO and IEC 80369 series. There are also some *medical devices* and *accessories* within the *applications* of the ISO and IEC 80369 series *applications* that incorporate a *Luer connector*. Those that present no unacceptable *risk* to the *patient* from an *unintended connection* to a *medical device* or *accessory* within intravascular or hypodermic *application* are suitable for consideration for the use of the *Luer connector* as specified in ISO 80369-7.

ISO 80369-20 specifies the common *test methods* for assessing the basic performance requirements specified in ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 for *small-bore connectors*.

ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 specify the dimensional requirements for the interfaces of the *connectors* and the specific performance requirements for assessing the interconnectability of the *connector*-mating halves.

The designs and dimensions of *small-bore connectors* specified in ISO 80369-2, ISO 80369-3, IEC 80369-5, ISO 80369-6 and ISO 80369-7 have been successfully assessed according to the requirements of this document (i.e. have been proven to be acceptable with regard to the *risk* of *misconnection* with the other *connectors* of this series).

The *risks* of changing to these new *small-bore connectors* should be assessed before these *small-bore connectors* are incorporated into *medical devices* as they will when the relevant particular *medical device* standards are revised.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

In this document the following verbal forms are used.

— “Shall” indicates requirements.

— “Should” indicates recommendations.

— “May” indicates permissions.

— "Can" indicates possibility or capability.

This document uses italic type to distinguish defined terms from the rest of the text. It is important for the correct understanding of this document that those defined terms are identifiable throughout the text of this document. A list of the defined terms used in italics in this document is given in Annex G.