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BSI Standards Publication

Enteral feeding systems – Design and testing

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This British Standard is the UK implementation of EN ISO 20695:2020. It is identical to ISO 20695:2020. It supersedes BS EN 1615:2000 and BS EN 1618:1997, which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

Enteral feeding systems - Design and testing (ISO 20695:2020)

Systèmes de nutrition entérale - Conception et essais (ISO 20695:2020)

Systeme zur enteralen Ernährung - Ausführung und Prüfung (ISO 20695:2020)

This European Standard was approved by CEN on 29 November 2019.

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European foreword

This document (EN ISO 20695:2020) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2020, and conflicting national standards shall be withdrawn at the latest by April 2023.

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

This document supersedes EN 1618:1997 and EN 1615:2000.

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The text of ISO 20695:2020 has been approved by CEN as EN ISO 20695:2020 without any modification.

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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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This document was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in collaboration with ISO Technical Committee TC 84, *Devices for administration of medicinal products and catheters*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Introduction

Enteral feeding systems are intended to facilitate the delivery of enteral nutrition, medications and hydration to, or aspiration of gastric content from, humans. They are designed to pass enteral fluids or substances through the nose or mouth, or by gastrostomy, jejunostomy or oesophagostomy. Enteral feeding catheters are terminally placed in the stomach, duodenum, or jejunum.

The requirements and test methods of this document are specified so that, when used in current clinical practice, these medical devices do not compromise the clinical condition or the safety of patients.

Incidents have been reported of enteral fluids or substances being administered via incorrect routes, including intravenously and into the airway. An international effort has been made to reduce these incidents and two series of International Standards have been developed to provide application specific connectors:

— ISO 80369-3 specifies connectors intended for use between an enteral giving set, enteral extension sets, enteral syringes, enteral catheters, and enteral accessories;

— ISO 18250-3 specifies connectors intended for use between an enteral giving set, an enteral accessory and an enteral reservoir.

The use of these enteral-specific connectors has been specified in this document as well as small-bore connectors as specified in ISO 80369-1:2018, Clause 6.

ISO 80369-3 and ISO 18250-3 ensure that connectors for enteral giving sets, enteral extension sets, enteral syringes, enteral feeding catheters and enteral accessories are unique and are not able to be connected to other small-bore connectors specified in the ISO 80369 series for the following applications: intravascular and hypodermic, breathing systems and driving gases, urethral and urinary, limb cuff inflation and neuraxial systems.

The small-bore connectors and reservoir connectors, as defined in ISO 80369-3 and ISO 18250-3, respectively, for use in enteral applications should not, but may connect with the following connectors/ports in common use within the same environment:

— the cones and sockets of ISO 5356-1 and ISO 5356-2;

— the temperature sensor ports made in conformity with ISO 80601-2-74:2017, Annex EE;

— the nipples of EN 13544-2 and EN 13544-2+A1.

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.

The verbal forms used in this document are as follows:

— “shall” means conformity with a requirement or a test is mandatory for conformity with this document,

— “should” means conformity with a requirement or a test is recommended but is not mandatory for conformity with this document, and

— “may” is used to describe a permissible way to achieve conformity with a requirement or test.

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Enteral feeding systems – Design and testing

1 Scope

This document specifies requirements for enteral feeding systems comprising enteral giving sets, enteral extension sets, enteral syringes, enteral feeding catheters, and enteral accessories.

This document is not applicable to oral syringes.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 7886-2:1996, *Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly process*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 18250-3:2018, *Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 3: Enteral applications*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 80369-1, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-3, *Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications*

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