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In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood

Dispositifs médicaux de diagnostic in vitro — Récipients à usage unique pour le prélèvement d'échantillons d'origine humaine autres que le sang

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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.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic 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.

In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood

1 Scope

This document specifies requirements and test methods for specialized single-use evacuated and non-evacuated containers, intended by their manufacturers, for the primary containment and preservation of specimens, other than blood specimens, derived from the human body, for the purposes of in vitro diagnostic examination. It is not intended to cover specimen containers for forensic investigations.

Examples of such specimens include, but are not limited to, cerebral spinal fluid (CSF), faeces, infected bodily fluids, saliva, ejaculate, sputum, urine, tissue samples.

Specimens and types of devices specifically excluded are specialized containers for cryo-preservation, samples for nucleic acid testing and swabs.

NOTE Requirements and test methods for evacuated and non-evacuated single-use human venous blood specimen collection containers are specified in ISO 6710.

This document does not specify requirements for auxiliary devices used in conjunction with specimen containers.

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 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
container
vessel, whether evacuated or not, intended to contain a *specimen* (3.17), together with any container *accessory* (3.5) and *additive* (3.9), with *closure* (3.4) in place

[SOURCE: ISO 6710:2017, 3.4]