



NSAI
Standards

Irish Standard
I.S. EN ISO 6717:2021

In vitro diagnostic medical devices - Single-use containers for the collection of specimens from humans other than blood (ISO 6717:2021)

I.S. EN ISO 6717:2021

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Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN ISO 6717:2021 is the adopted Irish version of the European Document EN ISO 6717:2021, In vitro diagnostic medical devices - Single-use containers for the collection of specimens from humans other than blood (ISO 6717:2021)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 6717

September 2021

ICS 11.100.10

Supersedes EN 14254:2004

English Version

**In vitro diagnostic medical devices - Single-use containers
for the collection of specimens from humans other than
blood (ISO 6717:2021)**

Dispositifs médicaux de diagnostic in vitro - Récipients
à usage unique pour le prélèvement d'échantillons
d'origine humaine autres que le sang (ISO 6717:2021)

In-vitro-Diagnostika - Einmalgefäße für
Untersuchungsgut vom Menschen mit Ausnahme von
Blutproben (ISO 6717:2021)

This European Standard was approved by CEN on 1 August 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a 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 member.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EN ISO 6717:2021 (E)

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European foreword

This document (EN ISO 6717:2021) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" in collaboration with Technical Committee CEN/TC 140 "In vitro diagnostic 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 March 2022, and conflicting national standards shall be withdrawn at the latest by September 2024.

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 14254:2004.

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

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Endorsement notice

The text of ISO 6717:2021 has been approved by CEN as EN ISO 6717:2021 without any modification.

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INTERNATIONAL STANDARD

**ISO
6717**

First edition
2021-08

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*



Reference number
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ISO 6717:2021(E)

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).

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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 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]

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