

STN	Diagnostické zdravotnícke pomôcky in vitro Jednorazové nádoby na odber iných ľudských vzoriek ako krv (ISO 6717: 2021)	STN EN ISO 6717 85 1030
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In vitro diagnostic medical devices - Single-use containers for the collection of specimens from humans other than blood (ISO 6717:2021)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/21

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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)

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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of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by September 2024.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.

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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.

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
ISO 6717:2021(E)

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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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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).

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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.

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