ICS 11.100.10 SLOVENSKÁ TECHNICKÁ NORMA Január 2022

STN	**Diagnostické zdravotnícke pomôcky in vitro Jednorazové nádoby na odber iných ľudských vzoriek ako krv (ISO 6717: 2021)**	**STN EN ISO 6717** 85 1030

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

Obsahuje: EN ISO 6717:2021, ISO 6717:2021

Oznámením tejto normy sa od 30.09.2024 ruší
STN EN 14254 (85 1030) z januára 2005

134036

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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 6717:2021 E

Contents

Page

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of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by September 2024.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

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

INTERNATIONAL STANDARD **ISO 6717:2021(E)**

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.

