Single-use containers for human venous blood specimen collection (ISO 6710:2017)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 6710:2017 sisaldab Euroopa standardi EN ISO 6710:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 6710:2017 consists of the English text of the European standard EN ISO 6710:2017.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 06.09.2017.	Date of Availability of the European standard is 06.09.2017.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.20

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 6710

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Supersedes EN 14820:2004

English Version

Single-use containers for human venous blood specimen collection (ISO 6710:2017)

Récipients non réutilisables pour prélèvements de sang veineux humain (ISO 6710:2017)

Gefäße zur einmaligen Verwendung für die venöse Blutentnahme (ISO 6710:2017)

This European Standard was approved by CEN on 23 August 2017.

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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 6710:2017 E

European foreword

This document (EN ISO 6710:2017) 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 218, and conflicting national standards shall be withdrawn at the latest by September 2020.

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 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

This document supersedes EN 14820:2004, of which the following has been changed:

— Clause "Introduction" has been updated;

— Clause "Scope" has been updated and phrased clearer. Blood culture bottles have been excluded from this standard, as it does not address the special needs for this kind of testing;

— Clause "Normative references" has been updated;

— Clause 'Terms and definitions" has been updated and extended;

— Clause "Materials" has been updated;

— Clause "Nominal liquid capacity" has been shortened and renamed to "Draw volume";

— Clause "Graduation and fill lines" has been deleted;

— Clause "Design" has been updated;

— Clause "Construction" has been updated and shortened;

— Clause "Sterility and special microbiological states" has been technically revised;

— Clause "Additives" has been updated and shortened;

— Clause "Information supplied by the manufacturer" has been updated to meet current general requirements (except local requirements), and renamed to "Marking and labelling";

— Clause "Receptacle and additive identification" has been updated and renamed to "Container identification". Table "Letter codes identifying the more common additives for blood specimen receptacles" within this clause has been renamed to "Letter codes for identifying additives and accessories" and extended by additional entries for additives;

— Tests in Normative Annexes A to D have been updated in alignment with the requirements in the body part of the standard. Annex A "Test for nominal liquid capacity and graduation marks, for non-evacuated blood specimen receptacles" was renamed to "Draw volume test for non-evacuated containers". Annex B "Test for draw volume for evacuated receptacles" was renamed to "Draw volume test for evacuated containers" and a figure was added for better explanation. Annex C "Test for leakage from the closure of a receptacle" was renamed to "Test for leakage of container". Annex D "Test for the robustness of a receptacle that is intended for centrifugations" was renamed to "test for robustness of the container";

— Normative Annex E "Concentrations of additives and volume of liquid additives" has been added;

— Informative Annex F "Recommended colour codes for identifying additives and accessories" has been added;

— The Bibliography has been updated.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA', the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 15223-1	EN ISO 15223-1:2016	ISO 15223-1:2016

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 6710:2017 has been approved by CEN as EN ISO 6710:2017 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the essential requirements of Directive 98/79/EC [OJ L 331] aimed to be covered

This European standard has been prepared under a Commission's standardisation request, M/252, concerning the development of European standards relating to *in vitro* diagnostic medical devices, to provide one voluntary means of conforming to essential requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [OJ L 331].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 98/79/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with Essential Requirements Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex *I* of Directive 98/79/EC [OJ L 331]

Essential Requirements of Directive 98/79/EC	Clause(s) / subclause(s) of this EN	Remarks / Notes
B.1.2	4.2, 5, 6.1, 6.2, 7.1, Annex C	Covered for leakage from the container during use. Not covered for storage and transport.
B.2.1	4.3, 6.1, 6.2, 6.3, 7.1, Annex C	Covered for leakage from the container during use and easy handling.
B.2.3	8.2	Covered for ensuring the container is sterile or in a special microbiological state. Does not cover other aspects of this ER including labelling, storage and transport.
B.2.4	8.2	

Essential Requirements of Directive 98/79/EC	Clause(s) / subclause(s) of this EN	Remarks / Notes
B.3.1	5	Covered for draw volume.
B.3.3	5, 7.1, 7.2	Covered for physical characteristics (sharp edges etc.) and for use with centrifuges.
B.4.1	Annex A, Annex B	Covered for accuracy of measurement within appropriate accuracy limits in the first sentence of this ER.
B.8.4 (b)	10.3 d)	
B.8.4 (c)	10.3 d) third indent	Covered for sterility.
B.8.4 (d)	10.3 b)	Only covered if the batch code is preceded by the word 'LOT'.
B.8.4 (e)	10.3 c)	
B.8.4 (h)	10.3 d) fifth intent	Covered for storage.

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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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 on 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 the following URL: 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*.

This second edition cancels and replaces the first edition (ISO 6710:1995), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the Scope has been updated and phrased clearer. Blood culture bottles have been excluded from this document, as it does not address the special needs for this kind of testing;

— Clause 3 has been updated and extended;

— Clause 4 has been updated;

— Clause 5 has been shortened and renamed to "Draw volume";

— Clause 6 has been updated;

— Clause 8 has been technically revised and renamed to "Sterility and special microbiological states";

— Clause 9 has been extended;

— Clause 10 has been slightly updated to meet current general requirements (except local requirements);

— Table 1 has been extended by additional entries for additives. It has been reduced to the specified letter codes, while the information on recommended colour codes for identifying additives has been moved to a new Annex F (for clarification, see Introduction);

— tests in Annexes A to D have been updated in alignment with the requirements in the body of this document;

— Annex E has been completely revised;

— references in Clause 2 and Bibliography have been updated.