BSI Standards Publication

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

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 6710:2017. It is identical to ISO 6710:2017. It supersedes BS EN 14820:2004, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

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

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Compliance with a British Standard cannot confer immunity from legal obligations.

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EUROPEAN STANDARD EN ISO 6710
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ICS 11.040.20 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

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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.

Contents

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.

Introduction

ISO 6710 was first published in 1995. With the first revision starting in the year 2000, the Vienna Agreement was applied to develop the updated edition of this document in parallel between ISO and CEN.

However, in 2002 the parallel ballot on ISO 6710, respectively prEN ISO 6710, failed on ISO level. The ongoing development was continued only on European level and led finally to the publication of EN 14820:2004. Although, during the development, no consensus could be reached between the CEN member states to add a specification for a common colour code for identifying containers with different additives.

The EU commission considered the absence of colour code specifications as potential safety risk and submitted in 2006 the standardization mandate M/384 to CEN with the request to solve the issue. But even with this confirmed need it was not possible to find a consensus between the CEN members.

Based on a Swedish standardization proposal in 2014, this subject was raised again and led finally to the initiation of the revision of ISO 6710:1995. The Vienna Agreement was applied in order to revise as well EN 14820:2004 with the final goal again to develop an International Standard in parallel with a harmonized European Standard.

During the development, it was recognized that at least recommendations for appropriate colour code specifications should be amended. In order to avoid further disputes on this subject, it was decided to add these recommendations in Annex F. This provides the potential users the possibility of a smooth implementation of the colour code identification without being under pressure to comply with this document in this subject. This way of introducing a common colour code allows manufacturers and/or users in healthcare to grant an evaluation phase. If there will be a higher acceptance after the publication of this document, with the next revision there is the intention to possibly move the content of Annex F to the normative part of this document.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this document.

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

1 Scope

This document specifies requirements and test methods for evacuated and non-evacuated single-use venous blood specimen containers.

It does not specify requirements for blood collection needles, needle holders, blood culture receptacles or “arterial” blood gas collection devices that can be used for venous blood.

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 medical device labels, labelling and information to be supplied — 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:

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

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

3.1
accessory
component inside the *container* (3.4) which is intended by the manufacturer to assist in the collection, or mixing, or separation of the *specimen* (3.15)

Note 1 to entry: Examples of accessories are small plastic inert balls or a separate gel found in a serum or plasma container designed to separate the serum or plasma from the cells after centrifugation.

3.2
additive
substance (other than inside surface treatments designed to be irremovable) that is placed in the *container* (3.4) in order to facilitate the creation of the desired sample

3.3
closure
component by which the *container* (3.4) is sealed, which may consist of several parts

3.4
container
vessel, whether evacuated or not, intended to contain a *specimen* (3.15), together with any container *accessory* (3.1) and *additive* (3.2), with *closure* (3.3) in place

3.5
container interior
inner surface of the *container* (3.4) exposed to the *specimen* (3.15)