BS EN ISO 6710:2017

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 It supersedes BS EN 14820:2004, which is withdrawn.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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Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by March 218, and conflicting national standards shall be withdrawn at the latest by September 2020.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";