BS EN ISO 8536-15:2022+A1:2023

BSI Standards Publication

Infusion equipment for medical use

Part 15: Light-protective infusion sets for single use

Documents
Document Sharing Hub

Full document details: BS EN ISO 8536-15:2022+A1:2023

National foreword

This British Standard is the UK implementation of EN ISO 8536-15:2022+A1:2023. It is identical to ISO 8536-15:2022 incorporating amendment 1:2023. It supersedes BS EN ISO 8536-15:2022, which is withdrawn.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 committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2023
Published by BSI Standards Limited 2023

ISBN 978 0 539 22522 8

ICS 11.040.20

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

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 March 2022.

Amendments/corrigenda issued since publication

Date	Text affected
31 March 2023	Implementation of ISO amendment 1:2023 with CEN endorsement A1:2023: Normative references, subclause 6.4.3, and Bibliography amended

Documents
Document Sharing Hub

Full document details: BS EN ISO 8536-15:2022+A1:2023

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-15:2022+A1

March 2023

ICS 11.040.20

English Version

Infusion equipment for medical use - Part 15: Light-protective infusion sets for single use (ISO 8536-15:2022)

Matériel de perfusion à usage médical - Partie 15: Perfuseurs photoprotecteurs à usage unique (ISO 8536-15:2022)

Infusionsgeräte zur medizinischen Verwendung - Teil 15: Lichtbeständige Infusionsgeräte zur einmaligen Verwendung (ISO 8536-15:2022)

This European Standard was approved by CEN on 21 February 2022.

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, 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 United Kingdom.

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

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

© 2022 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members

Ref. No. EN ISO 8536-15:2022: E

Documents
Document Sharing Hub

Full document details: BS EN ISO 8536-15:2022+A1:2023

European foreword

This document (EN ISO 8536-15:2022) 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 205 “Non-active 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 September 2022, and conflicting national standards shall be withdrawn at the latest by September 2022.

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.

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 website.

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 8536-15:2022 has been approved by CEN as EN ISO 8536-15:2022 without any modification.

European foreword to amendment A1

This document (EN ISO 8536-15:2022/A1:2023) 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 205 “Non-active 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 September 2023, and conflicting national standards shall be withdrawn at the latest by September 2023.

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.

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 website.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 8536-15:2022/Amd 1:2023 has been approved by CEN as EN ISO 8536-15:2022/A1:2023 without any modification.

AVA Documents Document Sharing Hub

Full document details: BS EN ISO 8536-15:2022+A1:2023

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 General requirements **1**
5 Materials **1**
6 Physical requirements **2**
6.1 General 2
6.2 Transparency 2
6.3 Light-protective performance 2
6.4 Decolourization 2
7 Chemical requirements **2**
8 Biological requirements **2**
9 Labelling **3**
10 Packaging **3**
11 Disposal **3**
Annex A (normative) **Determination of light transmittance** **4**
Annex B (normative) **Decolourization test – physical method** **6**
Annex C (normative) **Chemical method for decolourization test – visual colorimetry** **7**
Bibliography **8**

© ISO 2022 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 8536-15:2022+A1:2023

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 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 8536 series can be found on the ISO website.

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.

© ISO 2022 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 8536-15:2022+A1:2023