BS EN ISO 1135-3:2017

BSI Standards Publication

Transfusion equipment for medical use

Part 3: Blood-taking sets for single use (ISO 1135-3:2016)

bsi.

This British Standard is the UK implementation of EN ISO 1135-3:2017. It is identical to ISO 1135-3:2016.

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.

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

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EUROPEAN STANDARD **EN ISO 1135-3**

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English Version

Transfusion equipment for medical use - Part 3: Blood-taking sets for single use (ISO 1135-3:2016)

Matériel de transfusion à usage médical - Partie 3: Appareils non réutilisables pour prélèvement sanguin (ISO 1135-3:2016)

Transfusionsgeräte zur medizinischen Verwendung - Teil 3: Blutentnahmegeräte zur einmaligen Verwendung (ISO 1135-3:2016)

This European Standard was approved by CEN on 24 August 2016.

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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

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European foreword

This document (EN ISO 1135-3:2017) 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 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 August 2017, and conflicting national standards shall be withdrawn at the latest by August 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] 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.

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.

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 1— Correlations between undated 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 3696	EN ISO 3696:1995	ISO 3696:1987
ISO 7864	EN ISO 7864:2016	ISO 7864:2016

ISO 11607-1	EN ISO 11607-1:2009 + A1:2014	ISO 11607-1:2006 plus ISO 11607-1 Amd 1:2014
ISO 14644-1:2015	EN ISO 14644-1:2015	ISO 14644-1:2015
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012

Endorsement notice

The text of ISO 1135-3:2016 has been approved by CEN as EN ISO 1135-3:2017 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request *'M/295 concerning the development of European standards related to medical devices'* to provide a voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

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 93/42/EEC as amended by 2007/47/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 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to Table 1 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 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
7.2	3.3, 5.1, 5.2, 5.3, Clause 6, Clause 7, A.1, A.2	The part of ER 7.2 relating to packaging is not addressed (for packaging see Clause 9 of this standard).
7.3 (first part only)	Clause 4, 5.1, 5.2, 5.3, Clause 6, Clause 7, A.1, A.2	
7.5	5.2, 5.3, Clause 7, A.2	Only the first paragraph is covered. Presumption of conformity with the Essential Requirements relating to the biological evaluation can only be provided if the manufacturer chooses to apply the ISO 10993- series standards.

7.6	5.1, 5.2, 5.3, A.1, A.2	
8.1	3.4, 3.5, Clause 5	The part of ER 8.1 relating to handling is not addressed. Manufacturing processes are not covered. The reduction of the risk of infection is not fully covered.
8.3	3.3, 3.4, 5.9, Clause 9	
8.4	7.2	Only the sterilization method is covered.
8.5	5.1, A.1	
8.7	8.2, 8.3	
9.1	5.4, 5.5	The second sentence of ER 9.1 is not addressed. Coverage of this ER is partly provided by normative reference to EN ISO 7864.
9.2 (first indent)	Clause 5, 7.1	Covered in respect of the following: - Particulate contamination; - Leakage; - Tensile strength; - Dimensions; - Physical characteristics of tube and needle.
9.2 (second indent)	5.2	Covered in respect of the following: - Variations in pressure.
9.2 (fourth indent)	Clause 4	Covered in respect of the following: - Undesirable effects on blood or fluid used.
12.7.1	5.3	Only tensile strength is addressed.
13.1	Clause 8	Only requirements for labelling are covered.
13.2	8.1, 8.2, 8.3	The final sentence is not addressed.
13.3 b)	8.2 b), 8.3 b)	
13.3 c)	8.2 c), 8.3 c)	

13.3 d)	8.2 d), 8.3 d)	Only covered if the batch number is preceded by the word "LOT".
13.3 e)	8.2 e), 8.3 e)	
13.3 f)	8.2, 8.3	Requirement "indication of single use must be consistent across the Community" is not addressed in the standard.
13.4	8.2, 8.3	13.4 is addressed regarding to the label.

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 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.

The committee responsible for this document is 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 1135-3:1986), which has been technically revised with the following changes:

— part title has been amended by "for single use" in alignment with the other parts of ISO 1135;

— figures have been updated;

— subclause 3.6, "Designation examples" has been deleted;

— physical, chemical and biological requirements have been aligned with ISO 1135-4;

— Clause 10, "Disposal" has been added;

— Annexes A, B and C have been aligned with ISO 1135-4;

— all references have been updated.

ISO 1135 consists of the following parts, under the general title *Transfusion equipment for medical use*:

— *Part 3: Blood-taking sets for single use*

— *Part 4: Transfusion sets for single use, gravity feed*

— *Part 5: Transfusion sets for single use with pressure infusion apparatus*

Transfusion equipment for medical use —

Part 3:
Blood-taking sets for single use

1 Scope

This part of ISO 1135 specifies requirements for types of blood-taking sets for medical use in order to ensure functional interchangeability of transfusion equipment. It is applicable to sterilized blood-taking sets intended for single use only.

This part of ISO 1135 also aims to provide

a) specifications relating to the quality and performance of materials used in transfusion equipment, and

b) a unified presentation of terms for such equipment.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 1135.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 7864, *Sterile hypodermic needles for single use*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14644-1:2015, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 General requirements

3.1 Types of sets

The blood-taking set shall consist of the blood-taking assembly and the air-outlet assembly, which may be separate or combined.

A diagram of a typical blood-taking set is illustrated in Figure 1.