BS EN ISO 1135-4:2015

Incorporating corrigendum February 2016

BSI Standards Publication

Transfusion equipment for medical use

Part 4: Transfusion sets for single use, gravity feed

National foreword

This British Standard is the UK implementation of EN ISO 1135-4:2015. Together with BS EN ISO 1135-5:2015, it supersedes BS EN ISO 1135-4:2012 which is withdrawn.

This standard has been technically revised with the following changes:

- the scope has been restricted to gravity feed applications and the whole document aligned accordingly;
- transfusion sets for single use used in conjunction with pressure infusion apparatus are now covered by BS EN ISO 1135-5:2015;
- clause 3.3 "Designation examples" has been deleted;
- clause 7.6 "Assessment of blood component depletion" and clause 7.7 "Assessment of damage to blood components" have been added;
- the Normative references and the Bibliography have been updated;
- some minor editorial changes were introduced in the whole document.

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.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 January 2016.

Amendments/corrigenda issued since publication

Date	Text affected
29 February 2016	Implementation of CEN Correction Notice 27 January 2016: Table ZA.1 replaced

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 1135-4

December 2015

ICS 11.040.20

Supersedes EN ISO 1135-4:2012

English Version

Transfusion equipment for medical use - Part 4: Transfusion sets for single use, gravity feed (ISO 1135-4:2015)

Matériel de transfusion à usage médical - Partie 4: Appareils de transfusion non réutilisables à alimentation par gravité (ISO 1135-4:2015)

Transfusionsgeräte zur medizinischen Verwendung - Teil 4: Transfusionsgeräte für Schwerkrafttransfusionen zur einmaligen Verwendung (ISO 1135-4:2015)

This European Standard was approved by CEN on 24 July 2015.

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, 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 1135-4:2015 E

European foreword

This document (EN ISO 1135-4:2015) 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 June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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.

Together with EN ISO 1135-5:2015 this document supersedes EN ISO 1135-4:2012.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 1135-4:2015 has been approved by CEN as EN ISO 1135-4:2015 without any modification.

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 ISO or IEC standard, as listed in Table 1.

NOTE The way in which these references 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 594-1	---	ISO 594-1:1986
ISO 594-2	---	ISO 594-2:1998
ISO 3696	EN ISO 3696:1995	ISO 3696:1987
ISO 3826-1:2013	EN ISO 3826-1:2013	ISO 3826-1:2013
ISO 3826-2	EN ISO 3826-2:2008	ISO 3826-2:2008
ISO 7864	EN ISO 7864:1995	ISO 7864:1993
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 10993-4	EN ISO 10993-4:2009	ISO 10993-4:2002 plus ISO 10993-4 AMD 1:2006
ISO 14644-1	EN ISO 14644-1:1999	ISO 14644-1:1999
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Medical devices

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the 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 / Directive 90/385/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 of References, 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 Directive 93/42/EEC on medical devices

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
3.2, 5.1, 5.2, 5.3, Clause 6, Clause 7	7.2	The part of ER 7.2 relating to packaging is not addressed (for packaging see Clause 9 of this standard).
Clause 4, 5.1, 5.2, 5.3, Clause 6, Clause 7	7.3	ER covered by biological evaluation
5.2, 5.3, 5.10, 8.2, 8.3, A.2, A.4	7.5	Only the first paragraph is covered.
5.1, 5.3	7.6	
3.2, Clause 5	8.1	
5.12, Clause 8, Clause 9	8.3	Maintenance of sterility in storage is covered.
7.2	8.4	Sterilization process is covered.
5.1, A.1	8.5	

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
8.2, 8.3	8.7	
5.4, 5.11	9.1	The second sentence of ER 9.1 is not addressed. 5.4 refers to ISO 3826-1. 5.11 refers to ISO 594-1 and ISO 594-2.
Clauses 3, 4, 5, 6, 7	9.2	
5.2, 5.3, A.2	12.7	Only 12.7.1 is addressed. Only tensile strength is addressed.
Clause 8	13.1	
8.2, 8.3	13.2	ISO 15223-1 and ISO 3826-2 are addressed when using symbols.
8.2 a), b), c), d), e), f), g), i), j), k), 8.3 a), b), c), d), e), f), g)	13.3	The part of 13.3a) relating to the authorized representative is not addressed. Presumption of conformity to the rest of 13.3a) is only provided if the name and address of the manufacturer are given. 13.3b) is addressed in Clause 3.1 and 4.3. 13.3d) is only covered if the batch number is preceded by the word 'LOT'. 13.3f) Requirement “indication of single use must be consistent across the Community” is not addressed in the standard. 13.3g) and h) are not addressed in the standard.
8.2, 8.3	13.4	13.4 is addressed regarding to the label.

WARNING — Other requirements and other EU Directives 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This sixth edition of ISO 1135-4, together with the first edition of ISO 1135-5, cancels and replaces the fifth edition (ISO 1135-4:2012), which has been technically revised with the following changes:

— the scope has been restricted to gravity feed applications and the whole document aligned accordingly;

— transfusion sets for single use used in conjunction with pressure infusion apparatus are now covered by ISO 1135-5;

— 3.3 "Designation examples" has been deleted;

— the Normative references and the Bibliography have been updated;

— some minor editorial changes were introduced in the whole document.

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*

INTERNATIONAL STANDARD **ISO 1135-4:2015(E)**

Transfusion equipment for medical use —

Part 4: Transfusion sets for single use, gravity feed

1 Scope

This part of ISO 1135 specifies requirements for single use transfusion gravity sets for medical use in order to ensure their compatibility with containers for blood and blood components as well as with intravenous equipment.

Secondary aims of this part of ISO 1135 are to provide guidance on specifications relating to the quality and performance of materials used in transfusion sets, to present designations for transfusion set components, and to ensure the compatibility of sets with a range of cellular and plasma blood components.

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 594-1[1)], *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2[1)], *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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

ISO 3826-1:2013, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

ISO 3826-2, *Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets*

ISO 7864, *Sterile hypodermic needles for single use*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

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

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

1) To be replaced by ISO 80369-7.