



NSAI
Standards

Irish Standard
I.S. EN ISO 1135-4:2015

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

I.S. EN ISO 1135-4:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

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I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

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SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

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This document is based on:

EN ISO 1135-4:2015

Published:

2015-12-23

This document was published under the authority of the NSAI and comes into effect on:

2016-01-11

ICS number:

11.040.20

NOTE: If blank see CEN/CENELEC cover page

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN ISO 1135-4:2015 is the adopted Irish version of the European Document EN ISO 1135-4:2015, Transfusion equipment for medical use - Part 4: Transfusion sets for single use, gravity feed (ISO 1135-4:2015)

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

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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Correction Notice

Reference: EN ISO 1135-4:2015

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

Work Item: 00205273

Brussels, 2016-01-27

please include the following minor editorial correction(s) in the document related to:

the following language version(s) :

- English
- French
- German

for the following procedure :

- PQ/UQ
- Enquiry
- 2nd Enquiry
- Parallel Enquiry
- 2nd Parallel Enquiry
- Formal Vote
- 2nd Formal Vote
- Parallel Formal Vote
- 2nd Parallel Formal Vote
- UAP
- TC Approval
- 2nd TC Approval
- Publication
- Parallel Publication

It has been brought to our attention that this document, issued on 2015-12-23, requires modification.

Table ZA.1 has been replaced in the English version.

Please find enclosed the updated English version.

EUROPEAN STANDARD

EN ISO 1135-4

NORME EUROPÉENNE

EUROPÄISCHE NORM

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

EN ISO 1135-4:2015 (E)

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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.

EN ISO 1135-4:2015 (E)**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, Medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
3.2	7.2, 8.1	
3.3	13.3 b)	
4	1, 2, 3	
5.1	7.2	
5.2	7.6	
5.3	9.1, 12.7.1	
5.4	7.6	
5.5	12.8	
5.6	7.2	
5.7	12.8	
5.8	10, 12.8	
5.9	10, 12.8	

EN ISO 1135-4:2015 (E)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.10	8	
5.11	9.1	
5.12	8	
6	7	
7.1	7, 7.5	Presumption of conformity with the Essential Requirements relating to the biological evaluation can only be provided if the manufacturer chooses to apply the EN ISO 10993-series standards
7.2	8.4	
7.3	7.1, 7.2	
7.4	7.1, 7.2	
7.5	7.1, 7.2	
8	13	The part of 13.3.a) relating to the authorized representative is not addressed. 13.3.f) and 13.6.h) relating to single use are not fully addressed. 13.6.q) is not addressed.
9	5, 8.3	
10	13.6 n)	

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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**INTERNATIONAL
STANDARD**

**ISO
1135-4**

Sixth edition
2015-12-01

**Transfusion equipment for medical
use —**

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

Matériel de transfusion à usage médical —

*Partie 4: Appareils de transfusion non réutilisables à alimentation par
gravité*



Reference number
ISO 1135-4:2015(E)

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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