



NSAI
Standards

Irish Standard
I.S. EN ISO 8536-14:2018

Infusion equipment for medical use - Part 14:
Clamps and flow regulators for transfusion
and infusion equipment without fluid contact
(ISO 8536-14:2016)

I.S. EN ISO 8536-14:2018

Incorporating amendments/corrigenda/National Annexes issued since publication:

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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

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National Foreword

I.S. EN ISO 8536-14:2018 is the adopted Irish version of the European Document EN ISO 8536-14:2018, Infusion equipment for medical use - Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact (ISO 8536-14:2016)

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EUROPEAN STANDARD

EN ISO 8536-14

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2018

ICS 11.040.20

English Version

Infusion equipment for medical use - Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact (ISO 8536-14:2016)

Matériel de perfusion à usage médical - Partie 14:
Clamps et limiteurs de débit pour appareils de
transfusion et de perfusion sans contact à fluide (ISO
8536-14:2016)

Infusionsgeräte zur medizinischen Verwendung - Teil
14: Klemmen und Durchflussregler für Transfusions-
und Infusionsgeräte ohne Flüssigkeitskontakt (ISO
8536-14:2016)

This European Standard was approved by CEN on 19 December 2017.

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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.

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

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

Contents	Page
European foreword.....	3
Annex ZA (informative) Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered	5

European foreword

This document (EN ISO 8536-14:2018) 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 2018, and conflicting national standards shall be withdrawn at the latest by February 2021.

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.

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 references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between 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 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009

EN ISO 8536-14:2018 (E)

Endorsement notice

The text of ISO 8536-14:2016 has been approved by CEN as EN ISO 8536-14:2018 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 one voluntary means of conforming to essential requirements of 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. 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 the table 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	4, 5, 6	<p>Clause 4 covers ER 7.2 in respect of controlling fluid flow and avoiding puncturing of flexible tubing only.</p> <p>Clause 5 covers ER 7.2 in respect of material physical performance as follows:</p> <ul style="list-style-type: none"> • Tubing specifications • Operating temperature • Construction • Flow rates <p>Clause 6 covers ER 7.2 in respect of the following items only:</p> <ul style="list-style-type: none"> • Tubing specifications • Operating temperature • Construction • Flow rates <p>The part of ER 7.2 relating to packaging is not addressed.</p>
7.5	6.3, A.1	<p>Clause 6.3 covers ER 7.5, first para, first sentence in respect of controlling the flow rate of substances being delivered via the infusion set only.</p> <p>A.1 covers ER 7.5, first para, first sentence in respect of controlling the flow rate of substances being delivered via the infusion set only.</p> <p>ER 7.5, first para, second sentence and ER 7.5, paragraphs two and three are not covered.</p>
7.6	6.3, A.1	<p>ER 7.6 is covered by Clause 6.3 but only to the extent that the clamp must ensure complete occlusion of the fluid pathway.</p> <p>ER 7.6 is covered by A.1 but only to the extent that the clamp must ensure complete occlusion of the fluid pathway.</p>

9.1	4	ER 9.1 is covered by Clause 4 in respect of the design of the clamp so that accidental operation of the clamp is avoided and flexible tubing is not damaged during operation only.
12.7.1	4	ER 12.7.1 is covered by Clause 4 in respect of the design of the clamp so that accidental operation of the clamp is avoided and flexible tubing is not damaged during operation only.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to the 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 products falling within the scope of this standard.

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INTERNATIONAL STANDARD

ISO
8536-14

First edition
2016-11-15

Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact

Matériel de perfusion à usage médical —

*Partie 14: Clamps et limiteurs de débit pour appareils de transfusion
et de perfusion sans contact à fluide*



Reference number
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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

Contents

	Page
Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Design	1
5 Materials	2
6 Physical requirements	2
6.1 Tubing specifications	2
6.2 Operating temperature	2
6.3 Construction	2
6.4 Flow rates	3
Annex A (normative) Physical tests	4
Bibliography	5

ISO 8536-14:2016(E)

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*.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

- *Part 1: Infusion glass bottles*
- *Part 2: Closures for infusion bottles*
- *Part 3: Aluminium caps for infusion bottles*
- *Part 4: Infusion sets for single use, gravity feed*
- *Part 5: Burette infusion sets for single use, gravity feed*
- *Part 6: Freeze drying closures for infusion bottles*
- *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*
- *Part 8: Infusion sets for single use with pressure infusion apparatus*
- *Part 9: Fluid lines for single use with pressure infusion equipment*
- *Part 10: Accessories for fluid lines for single use with pressure infusion equipment*
- *Part 11: Infusion filters for single use with pressure infusion equipment*
- *Part 12: Check valves*
- *Part 13: Graduated flow regulators for single use with fluid contact*
- *Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*

Infusion equipment for medical use —

Part 14:

Clamps and flow regulators for transfusion and infusion equipment without fluid contact

1 Scope

This part of ISO 8536 specifies requirements for non-sterile clamps and flow regulators used as a subcomponent to control the flow of intravenous solutions and/or blood components through sterilized infusion and blood transfusion sets and blood bag assemblies without fluid contact.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

clamp

subcomponent applied externally to an infusion/transfusion equipment without fluid contact with an “on/off” function used to terminate or initiate the flow of fluid through the line

3.2

flow regulator

subcomponent with or without graduation applied externally to an infusion/transfusion equipment without fluid contact to control the flow of fluid through the line

3.3

flow rate

volume per time

4 Design

Clamps and flow regulators shall be designed for their application in controlling fluid transfer in infusion/transfusion equipment. These devices shall be designed for safe use, avoiding accidental operation, and shall not puncture or damage the flexible tubing during their operation.

Typical design for clamps and flow regulators is shown in [Figures 1 to 3](#).

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