

<b>STN</b>	<b>Infúzne prístroje používané v zdravotníctve. Časť 13: Odstupňované regulátory prietoku na jednorazové použitie s infúznymi súpravami (ISO 8536-13: 2016).</b>	<b>STN EN ISO 8536-13</b>  70 3350
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Infusion equipment for medical use - Part 13: Graduated flow regulators for single use with fluid contact (ISO 8536-13:2016)

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/17

Obsahuje: EN ISO 8536-13:2016, ISO 8536-13:2016

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Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2017  
Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.

EUROPEAN STANDARD

**EN ISO 8536-13**

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2016

ICS 11.040.20

English Version

## Infusion equipment for medical use - Part 13: Graduated flow regulators for single use with fluid contact (ISO 8536-13:2016)

Matériel de perfusion à usage médical - Partie 13:  
Régulateurs de débit gradués non réutilisables avec  
contact à fluide (ISO 8536-13:2016)

Infusionsgeräte zur medizinischen Verwendung - Teil  
13: Graduierte Durchflussregler zur einmaligen  
Verwendung mit Flüssigkeitskontakt (ISO 8536-  
13:2016)

This European Standard was approved by CEN on 17 September 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.

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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## European foreword

This document (EN ISO 8536-13:2016) 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 April 2017, and conflicting national standards shall be withdrawn at the latest by April 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, 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 ISO or IEC standard, as listed in Table 1.

**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 8536-4	EN ISO 8536-4:2013 + A1:2013	ISO 8536-4:2010 + Amd.1:2013
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 80000-4	EN ISO 80000-4:2013	ISO 80000-4:2006

**Endorsement notice**

The text of ISO 8536-13:2016 has been approved by CEN as EN ISO 8536-13:2016 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 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 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	5, 6, 7, 8	Clause 7 and Clause 8 refer to ISO 8536-4. The part of ER 7.2 relating to packaging is not addressed.
7.3	5, 6, 7, 8	Sections 7 and 8 refer to ISO 8536-4. ER covered by biological evaluation.

7.5	6.3, 6.4, A.2, A.3	Only the first sentence 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	6.2, 6.3, 6.4, A.1, A.2, A.3	
8.1	6.2, 6.3, 6.4, 7, 8, A.1, A.2, A.3	Sections 7 and 8 refer to ISO 8536-4. 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.
8.5	6.2, A.1	ER 8.5 is covered by 6.2 only for particulate contamination.
9.1	4	The second sentence of ER 9.1 is not addressed.
12.7	6.3, A.2	Only 12.7.1 is addressed. Only tensile strength is addressed.

**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 products falling within the scope of this standard.

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**Infusion equipment for medical use —  
Part 13:  
Graduated flow regulators for single  
use with fluid contact**

*Matériel de perfusion à usage médical —*

*Partie 13: Régulateurs de débit gradués non réutilisables avec contact  
à fluide*







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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](http://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](http://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](http://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 13:

# Graduated flow regulators for single use with fluid contact

## 1 Scope

This part of ISO 8536 specifies requirements for non-sterile, single-use graduated flow regulators used as subcomponents in sterilized infusion sets for single use to control the flow of intravenous infusion solutions with fluid contact under gravity feed conditions.

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 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

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

ISO 80000-4, *Quantities and units — Part 4: Mechanics*

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**