



**SLOVENSKI STANDARD**  
**SIST EN ISO 11663:2016**  
**01-januar-2016**

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**Kakovost tekočin za hemodializo in podobne terapije (ISO 11663:2014)**

Quality of dialysis fluid for haemodialysis and related therapies (ISO 11663:2014)

Qualität von Konzentraten für die Hämodialyse und verwandte Therapien (ISO 11663:2014)

Qualité des fluides de dialyse pour hémodialyse et thérapies apparentées (ISO 11663:2014)

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**Ta slovenski standard je istoveten z: EN ISO 11663:2015**

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**ICS:**

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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**en**

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EUROPEAN STANDARD

EN ISO 11663

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2015

ICS 11.040.40

English Version

## Quality of dialysis fluid for haemodialysis and related therapies (ISO 11663:2014)

Qualité des fluides de dialyse pour hémodialyse et thérapies apparentées (ISO 11663:2014)

Qualität von Konzentraten für die Hämodialyse und verwandte Therapien (ISO 11663:2014)

This European Standard was approved by CEN on 10 October 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.

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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**

<b>Contents</b>	Page
<b>Foreword</b> .....	<b>3</b>
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices</b> .....	<b>5</b>

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## Foreword

The text of ISO 11663:2014 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11663:2015 by 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 May 2016, and conflicting national standards shall be withdrawn at the latest by May 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.

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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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.

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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 — Correlation 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 13958	EN ISO 13958:2015 <sup>1</sup>	ISO 13958:2014
ISO 13959	EN ISO 13959:2015 <sup>2</sup>	ISO 13959:2014

1) To be published

2) To be published.

**EN ISO 11663:2015 (E)**

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 11663:2014 has been approved by CEN as EN ISO 11663:2015 without any modification.

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## 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 on 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 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 Directive 93/42/EEC on medical devices**

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	7.2	
3.13	7.3	
4.1	8	
1.3	13.6. (c)	

**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  
11663

Second edition  
2014-04-01

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**Quality of dialysis fluid for  
haemodialysis and related therapies**

*Qualité des fluides de dialyse pour hémodialyse et thérapies  
apparentées*

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Reference number  
ISO 11663:2014(E)

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Published in Switzerland

<b>Contents</b>		Page
<b>Foreword</b> .....		<b>iv</b>
<b>Introduction</b> .....		<b>v</b>
<b>1 Scope</b> .....		<b>1</b>
<b>2 Normative references</b> .....		<b>1</b>
<b>3 Terms and definitions</b> .....		<b>1</b>
<b>4 Requirements</b> .....		<b>6</b>
4.1 Microbiological contaminants in dialysis fluid.....		<b>6</b>
4.2 Chemical contaminants in dialysis fluid.....		<b>7</b>
<b>5 Tests for compliance with microbiological requirements</b> .....		<b>7</b>
<b>Annex A (informative) Rationale for the development and provisions of this International Standard</b> .....		<b>9</b>
<b>Annex B (informative) Reference tables from ISO 13959</b> .....		<b>12</b>
<b>Bibliography</b> .....		<b>15</b>

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SIST EN ISO 11663:2016

<https://standards.iteh.ai/catalog/standards/sist/ee9c27b3-9385-4b7c-b7e8-aff07556ad12/sist-en-iso-11663-2016>

## ISO 11663:2014(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](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 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 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This second edition cancels and replaces the first edition (ISO 11663:2009) which has been technically revised.