ICS 11.040.40 SLOVENSKÁ TECHNICKÁ NORMA Jún 2014

STN	**Kardiovaskulárne implantáty a mimotelové systémy Hemodialyzátory, hemodiafiltre, hemofiltre a hemokoncentrátory (ISO 8637: 2010 vrátane zmeny Amd 1: 2013)**	**STN EN ISO 8637** 85 6214

Cardiovascular implants and extracorporeal systems - Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (ISO 8637:2010, including Amendment 1 2013-04-01)

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. 05/14

Obsahuje: EN ISO 8637:2014, ISO 8637:2010, ISO 8637:2010/Amd 1:2013

Oznámením tejto normy sa ruší
STN EN 1283 (85 6214) z augusta 2001

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8637

January 2014

ICS 11.040.40

Supersedes EN 1283:1996

English Version

Cardiovascular implants and extracorporeal systems - Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (ISO 8637:2010, including Amendment 1 2013-04-01)

Implants cardiovasculaires et systèmes extracorporels - Hémodialyseurs, hémodiafiltres, hémofiltres et hémoconcentrateurs (ISO 8637:2010, Amendement 1 2013-04-01 inclus)

Kardiovaskuläre Implantate und extrakorporale Systeme - Hämodialysatoren, Hämodiafilter, Hämofilter und Hämokonzentratoren (ISO 8637:2010, einschließlich Änderung 1 2013-04-01)

This European Standard was approved by CEN on 1 December 2013.

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

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Foreword

The text of ISO 8637:2010, including Amendment 1 2013-04-01 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organisation for Standardization (ISO) and has been taken over as EN ISO 8637:2014 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 July 2014, and conflicting national standards shall be withdrawn at the latest by July 2014.

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 supersedes EN 1283:1996.

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 8637:2010 has been approved by CEN as EN ISO 8637:2014 without any modification.

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.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices *(1 of 2)*

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.1, 4.2, 4.3	7.2	
4.1	7.3	
4.1	7.4	Addressed only in general terms. Blood-contacting surfaces incorporating medicinal products, such as heparin, are not specifically addressed.
4.1, 6.4(n)	7.5	Addressed only in general terms. Typically, these devices do not incorporate materials containing phthalates.
4.2, 4.3, 6.1(h), 6.1(i), 6.2(e), 6.2(f), 6.2(h), 6.3(f), 6.3(g), 6.4(c), 6.4(f), 6.4(g), 6.4(i)	8.1	
4.2, 5.3	8.3	Addressed only in general terms.
4.2, 5.3	8.4	
4.4.3, 4.4.4, 4.4.5, 4.4.6	9.1	Connectors are specified to match tubing connectors specified in ISO 8638 for the blood compartment.
4.4.4	12.7.4	
6	13.1	
6.1, 6.2, 6.3, 6.4	13.2	The NOTE at the end of each clause allows the use of symbols from Harmonized Standards.

Table ZA.1 ***(2 of 2)***

Clause(s)/sub-clause(s) of this EN	**Essential Requirements (ERs) of Directive 93/42/EEC**	**Qualifying remarks/Notes**
6.1(a), 6.2(a), 6.3(a), 6.3(b), 6.4(a)	13.3 (a)	
6.1(b), 6.1(c), 6.2(b), 6.2(c), 6.3(c), 6.3(d), 6.4(b), 6.4(e)	13.3 (b)	
6.2(e), 6.3(f), 6.4(f)	13.3 (c)	
6.1(d), 6.2(d), 6.3(e)	13.3 (d)	
6.1(g), 6.2(g), 6.3(h)	13.3 (e)	
6.1(i), 6.2(h), 6.4(g)	13.3 (f)	
6.3(g)	13.3 (i)	
6.4(c), 6.4(d), 6.4(i)	13.3 (j)	
6.2(j), 6.4(d)	13.3 (k)	
6.1(h), 6.2(f), 6.4(f)	13.3 (m)	
6.4(a), 6.4(b), 6.4(e), 6.4(f), 6.4(g), 6.4(i), 6.4(f)	13.6 (a)	There is no requirement for the information in 13.3 (i) in the instructions for use. Instead, that information is required to be given on the outer container in which the device is sold.
6.4(h)	13.6 (b)	
6.4(l), 6.4(m)	13.6 (c)	
6.2(h), 6.4(g), 6.4(i)	13.6 (h)	
6.4(c), 6.4(d)	13.6 (i)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 8637

Third edition
2010-07-01

Cardiovascular implants and extracorporeal systems — Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

Implants cardiovasculaires et systèmes extracorporels — Hémodialyseurs, hémodiafiltres, hémofiltres et hémoconcentrateurs

Reference number
ISO 8637:2010(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 8637 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This third edition cancels and replaces the second edition (ISO 8637:2004), which has been technically revised.

Introduction

This International Standard is concerned with devices intended for haemodialysis, haemodiafiltration, haemofiltration and haemoconcentration in humans. The requirements specified in this International Standard will help to ensure safety and satisfactory function.

It was not found practicable to specify materials of construction. This International Standard therefore requires only that materials have been tested and that the methods and results are made available upon request. There is no intention to specify, or to set limits on, the performance characteristics of the devices because such restrictions are unnecessary for the qualified user and would limit the alternatives available when choosing a device for a specific application.

The dimensions of the blood ports and the dialysis fluid or filtrate ports have been specified to ensure compatibility of the device with the extracorporeal blood circuit specified in ISO 8638. The design and dimensions have been selected in order to minimize the risk of leakage of blood and the ingress of air.

This International Standard reflects the consensus of physicians, manufacturers and other interested parties for devices that are approved for clinical use. Conformance with this International Standard is voluntary and it does not supersede any national regulation.

INTERNATIONAL STANDARD **ISO 8637:2010(E)**

Cardiovascular implants and extracorporeal systems — Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

1 Scope

This International Standard specifies requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators, hereinafter collectively referred to as “the device”, for use in humans.

This International Standard is not applicable to:

— extracorporeal blood circuits;

— plasmafilters;

— haemoperfusion devices;

— vascular access devices;

— blood pumps;

— pressure monitors for the extracorporeal blood circuit;

— air detection devices;

— systems to prepare, maintain or monitor dialysis fluid;

— systems used to perform haemodialysis, haemodiafiltration, haemofiltration or haemoconcentration;

— reprocessing procedures and equipment.

NOTE Requirements for the extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters are specified in ISO 8638.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*