Südame-veresoonkonna implantaadid ja kehavälised süsteemid. Kehaväline vereringe hemodialüsaatoritele, verelahutusfiltritele ja verefiltritele (ISO 8638:2010)

Cardiovascular implants and extracorporeal systems - Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters (ISO 8638:2010)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 8638:2014 sisaldab Euroopa standardi EN ISO 8638:2014 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 8638:2014 consists of the English text of the European standard EN ISO 8638:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.01.2014.	Date of Availability of the European standard is 15.01.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8638

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Supersedes EN 1283:1996

English Version

Cardiovascular implants and extracorporeal systems - Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters (ISO 8638:2010)

Implants cardiovasculaires et systèmes extracorporels - Circuit sanguin extracorporel pour les hémodialyseurs, les hémodiafiltres et les hémofiltres (ISO 8638:2010)

Kardiovaskuläre Implantate und extrakorporale Systeme - Extrakorporaler Blutkreislauf bei Hämodialysatoren, Hämodiafiltern und Hämofiltern (ISO 8638:2010)

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

Ref. No. EN ISO 8638:2014 E

Foreword

The text of ISO 8638:2010 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 8638:2014 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 1283:1986.

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 8638:2010 has been approved by CEN as EN ISO 8638:2014 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

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, 6.3(q)	7.5	Addressed only in general terms. Although these devices can incorporate materials containing phthalates, there is no specific requirement that the presence of phthalates be indicated in the labelling.
4.4.1, 4.4.9	7.6	
4.2, 4.4.1, 4.4.6, 4.4.9, 6.2(e), 6.2(j), 6.4(f), 6.4(i), 6.4(n)	8.1	
4.2, 5.3	8.3	Addressed only in general terms.
4.2, 5.3	8.4	
4.4.2, 4.4.3, 4.4.4, 4.4.9.2	9.1	Connectors are specified to match tubing connectors specified in ISO 8637 for the blood compartment.
4.4.6.1, 4.4.10, 4.6	9.2	
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.
6.2(a), 6.3(a), 6.3(b), 6.4(a)	13.3 (a)	
6.2(b), 6.2(c), 6.3(c), 6.3(d), 6.4(b), 6.4(c)	13.3 (b)	
6.2(e), 6.3(f), 6.4(d)	13.3 (c)	

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.2(d), 6.3(e)	13.3 (d)	
6.2(f), 6.3(g)	13.3 (e)	
6.2(g), 6.4(e)	13.3 (f)	
6.3(h)	13.3 (i)	
6.2(j), 6.4(g), 6.4(i), 6.4(l), 6.4(m), 6.4(o)	13.3 (j)	
6.2(j), 6.4(f)	13.3 (k)	
6.2(i)	13.3 (m)	
6.4(a), 6.4(b), 6.4(c), 6.4(d), 6.4(e), 6.4(f), 6.4(g), 6.4(i), 6.4(l), 6.4(m), 6.4(o)	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(r)	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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Introduction

This International Standard is concerned with the extracorporeal blood circuit manufactured for single use and intended for use in conjunction with haemodialysers, haemodiafilters and haemofilters. The requirements specified in this International Standard for the extracorporeal blood circuit 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.

The dimensions of the connectors intended for connecting the extracorporeal blood circuit to a haemodialyser, haemodiafilter or haemofilter have been specified to ensure compatibility with these devices, as specified in ISO 8637. The design and dimensions have been selected in order to minimize the risk of leakage of blood and ingress of air. Connectors with either fixed or loose locking shells are permitted.

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 is not intended to supersede any national regulation.