SLOVENSKI STANDARD
kSIST FprEN ISO 8638:2013

01-september-2013

Vsadki (implantati) za srce in ožilje ter zunajtelesni pretočni sistemi - Zunajtelesni krvni obtok za hemodializatorje, hemodiafiltre in hemofiltre (ISO 8638:2010)

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

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

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

Ta slovenski standard je istoveten z: **FprEN ISO 8638**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

kSIST FprEN ISO 8638:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
FprEN ISO 8638

May 2013

ICS 11.040.40

Will supersede 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 draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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Foreword

The text of ISO 8638:2010 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 FprEN ISO 8638:2013 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN 1283:1996.

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.

Endorsement notice

The text of ISO 8638:2010 has been approved by CEN as FprEN ISO 8638:2013 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, 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)	

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
6.2(e), 6.3(f), 6.4(d)	13.3 (c)	
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.