SLOVENSKI STANDARD
kSIST FprEN ISO 7439:2011

01-april-2011

Intrauterini kontracepcijski pripomočki z bakrenim nosilcem - Zahteve in preskusi (ISO/FDIS 7439:2011)

Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO/FDIS 7439:2011)

Kupferhaltige Intrauterinpessare zur Empfängnisverhütung - Anforderungen, Prüfungen (ISO/FDIS 7439:2011)

Dispositifs intra-utérins contenant du cuivre - Exigences, essais (ISO/FDIS 7439:2011)

Ta slovenski standard je istoveten z: **FprEN ISO 7439**

ICS:

11.200	Načrtovanje družine. Mehanski kontracepcijski pripomočki	Birth control. Mechanical contraceptives

kSIST FprEN ISO 7439:2011 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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FINAL DRAFT
FprEN ISO 7439

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ICS 11.200

Will supersede EN ISO 7439:2009

English Version

Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO/FDIS 7439:2011)

Dispositifs intra-utérins contenant du cuivre - Exigences, essais (ISO/FDIS 7439:2011)

Kupferhaltige Intrauterinpessare zur Empfängnisverhütung - Anforderungen, Prüfungen (ISO/FDIS 7439:2011)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 285.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (FprEN ISO 7439:2011) has been prepared by Technical Committee ISO/TC 157 "Non-systemic contraceptives and STI barrier prophylactics" in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN ISO 7439:2009.

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.

Endorsement notice

The text of ISO/FDIS 7439:2011 has been approved by CEN as a FprEN ISO 7439:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

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 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 — Correspondence between this International Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 3, 4, 6	refers to 1st indent of ER 1
5.1	1, 2, 3, 4	refers to 1st indent of ER 1
5.2	1, 2, 9.2	refers to 1st indent of ER 1
5.3.1	1, 2, 9.2	refers to 1st indent of ER 1
5.3.2	3, 4	
5.3.3	1, 2	refers to 1st indent of ER 1
5.3.4	1, 2, 9.2	refers to 1st indent of ER 1
5.4	9.2, 12.7.1	
5.5.1	5	
5.5.2	4	
5.6	4	
5.7	3, 4	
6	7.1, 7.2, 8.1	
7.1	1, 2, 3, 4, 6, 8.1	refers to 1st indent of ER 1
7.6	2, 7.1, 7.2, 7.5	
7.7	1, 2, 3, 4, 6, 6.a	refers to 1st indent of ER 1
8	1, 2, 3, 4, 7.1, 7.2	refers to 1st indent of ER 1

9	8.3, 8.4, 8.5	
10	5, 8.3, 8.6	
11.1	13.1, 13.2	
11.2	13.3 a), 13.3 c) to f), 13.3 m)	The part of ER 13.3.a) relating to the information on the authorized representative is not addressed in this International Standard.
11.3	13.3 a), 13.3 d) to f)	The part of ER 13.3.a) relating to the information on the authorized representative is not addressed in this International Standard.
11.4	13.3 a) and 13.3 b), 13.3 k), 13.6 b), 13.6 e) and 13.6 f), 13.6 k), 13.6.l)	The part of ER 13.3.a) relating to the information on the authorized representative is not addressed in this International Standard.
11.5	13.4, 13.6 a) and 13.6 b), 13.6 d), 13.6.e), 13.6 i), 13.6 k) to n)	
		ER 13.3.f) is only partly addressed: safety issues. 13.6 h) is not addressed in this International Standard. 13.6 q) is not addressed in this International Standard.

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