SLOVENSKI STANDARD
SIST EN ISO 7439:2011

01-oktober-2011

Nadomešča:
SIST EN ISO 7439:2002/kprA1:2009
SIST EN ISO 7439:2009

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

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 7439:2011**

ICS:

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

SIST EN ISO 7439:2011 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7439

June 2011

ICS 11.200

Supersedes EN ISO 7439:2009

English Version

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

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

This European Standard was approved by CEN on 31 May 2011.

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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.

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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 (EN 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 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of an identical text or by endorsement, at the latest by December 2011, and conflicting national standards shall be withdrawn at the latest by December 2011.

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 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.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 7439:2011 has been approved by CEN as a EN 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.

INTERNATIONAL STANDARD

ISO 7439

Second edition
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Copper-bearing contraceptive intrauterine devices — Requirements and tests

Dispositifs intra-utérins contenant du cuivre — Exigences, essais

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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