SLOVENSKI STANDARD
SIST EN ISO 7439:2009

01-julij-2009

Nadomeģ a:
SIST EN ISO 7439:2002
SIST EN ISO 7439:2002/kprA1:2009

Intrauterini kontracepcijski pripomoļ ki z bakrenim nosilcem - Zahteve, preskusi (ISO 7439:2002)

Copper-bearing intra-uterine contraceptive devices - Requirements, tests (ISO 7439:2002)

Kupferhaltige Intrauterinpessare zur Empfängnisverhütung - Anforderungen, Prüfungen (ISO 7439:2002)

Dispositifs intra-utérins contenant du cuivre - Exigences, essais (ISO 7439:2002)

Ta slovenski standard je istoveten z: **EN ISO 7439:2009**

ICS:

11.200	Naļ rtovanje druģine. Mehanski kontracepcijski pripomoļ ki	Birth control. Mechanical contraceptives

SIST EN ISO 7439:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7439

May 2009

ICS 11.200

Supersedes EN ISO 7439:2002

English Version

Copper-bearing intra-uterine contraceptive devices - Requirements, tests (ISO 7439:2002)

Dispositifs intra-utérins contenant du cuivre - Exigences, essais (ISO 7439:2002)

Kupferhaltige Intrauterinpessare zur Empfängnisverhütung - Anforderungen, Prüfungen (ISO 7439:2002)

This European Standard was approved by CEN on 19 April 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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 United Kingdom.

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

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Ref. No. EN ISO 7439:2009: E

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Foreword

The text of ISO 7439:2002 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 EN ISO 7439:2009 by 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 November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 7439:2002.

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 EC Directive.

For relationship with EC 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, 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 7439:2002 has been approved by CEN as a EN ISO 7439:2009 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 Communities 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 European 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
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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 European 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 European 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 European 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 European Standard. 13.6 q) is not addressed in this European 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
2002-03-15

Copper-bearing intra-uterine contraceptive devices — Requirements, tests

Dispositifs intra-utérins contenant du cuivre — Spécifications, essais

Reference number
ISO 7439:2002(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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 7439 was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 157, *Mechanical contraceptives*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...".

This second edition cancels and replaces the first edition of ISO/TR 7439 (ISO/TR 7439:1981), which has been technically revised.

Annex ZZ forms a normative part of this International Standard.

Annex ZZ provides a list of corresponding International and European Standards for which equivalents are not given in the text.

For the purposes of this International Standard, the CEN annex regarding fulfilment of European Council Directives has been removed.