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

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 7439:2011 sisaldab Euroopa standardi EN ISO 7439:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 7439:2011 consists of the English text of the European standard EN ISO 7439:2011.
Standard on kinnitatud Eesti Standardikeskuse 30.06.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.06.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.06.2011.	Date of Availability of the European standard text 01.06.2011.
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English Version

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

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

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

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

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COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by December 2011, and conflicting national standards shall be withdrawn at the latest by December 2011.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.

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Introduction

Although every foreign object in the uterus exhibits a certain contraceptive effect, the method by which copper-bearing contraceptive intrauterine devices (IUDs) function is by the continuous release of copper ions. This interferes with some enzymatic functions, immobilizes sperm cells and inhibits fertilization. These contribute to the high effectiveness of the contraception.

The effectiveness of copper-bearing IUDs is many times greater than that of a simple plastics body.

Contraceptive IUDs containing copper are regarded as medical devices incorporating a substance with an ancillary action and are subject to the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Contraceptive IUDs whose primary purpose is to release progestogens are regulated as medicinal products and are subject to the European Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. The relevant essential requirements of Annex I to Directive 93/42/EEC apply as far as safety and performance-related device features are concerned. It is advisable that significant changes in the design of the IUD, insertion device, specification or insertion technique be validated.

Copper-bearing contraceptive intrauterine devices — Requirements and tests

1 Scope

This International Standard specifies requirements and tests for single-use, copper-bearing contraceptive intrauterine devices (IUDs) and their insertion instruments.

It is not applicable to IUDs consisting only of a plastics body or whose primary purpose is to release progestogens.

NOTE Some aspects of this International Standard can be applicable to medicated intrauterine devices and IUDs not containing copper.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14630:2008, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

European Pharmacopoeia (Ph. Eur.) [2)]

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
contraceptive intrauterine device
IUD
copper-bearing device placed in the uterine cavity for the purpose of preventing pregnancy

2) European Directorate for the Quality of Medicines (EDQM) of the Council of Europe.