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Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO 7439:2015)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/15

Obsahuje: EN ISO 7439:2015, ISO 7439:2015

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 7439

April 2015

ICS 11.200

Supersedes EN ISO 7439:2011

English Version

Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO 7439:2015)

Dispositifs contraceptifs intra-utérins contenant du cuivre - Exigences et essais (ISO 7439:2015)

Kupferhaltige Intrauterinpessare zur Empfängnisverhütung - Anforderungen und Prüfungen (ISO 7439:2015)

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Foreword

This document (EN ISO 7439:2015) has been prepared by Technical Committee ISO/TC 157 "Non-systemic contraceptives and STI barrier prophylactics" in collaboration 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of an identical text or by endorsement, at the latest by October 2015, and conflicting national standards shall be withdrawn at the latest by October 2015.

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Endorsement notice

The text of ISO 7439:2015 has been approved by CEN as EN ISO 7439:2015 without any modification.

INTERNATIONAL STANDARD

ISO 7439

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

Dispositifs contraceptifs intra-utérins contenant du cuivre — Exigences et essais

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics.*

This third edition cancels and replaces the second edition (ISO 7439:2011), of which it constitutes a minor revision.

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.

INTERNATIONAL STANDARD ISO 7439:2015(E)

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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 14630:2012, *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.)[1)]

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