

This document is a preview generated by EVS

Copper-bearing contraceptive intrauterine devices -  
Requirements and tests (ISO 7439:2023)



## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 7439:2023 sisaldab Euroopa standardi EN ISO 7439:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 7439:2023 consists of the English text of the European standard EN ISO 7439:2023.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.04.2023.	Date of Availability of the European standard is 19.04.2023.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile [standardiosakond@evs.ee](mailto:standardiosakond@evs.ee).

ICS 11.200

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht [www.evs.ee](http://www.evs.ee); telefon 605 5050; e-post [info@evs.ee](mailto:info@evs.ee)

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation and Accreditation:

Homepage [www.evs.ee](http://www.evs.ee); phone +372 605 5050; e-mail [info@evs.ee](mailto:info@evs.ee)

EUROPEAN STANDARD

EN ISO 7439

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2023

ICS 11.200

Supersedes EN ISO 7439:2015

English Version

## Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO 7439:2023)

Dispositifs contraceptifs intra-utérins contenant du  
cuivre - Exigences et essais (ISO 7439:2023)

Kupferhaltige Intrauterin pessare zur  
Empfängnisverhütung - Anforderungen und Prüfungen  
(ISO 7439:2023)

This European Standard was approved by CEN on 22 January 2023.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

## European foreword

This document (EN ISO 7439:2023) 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 October 2023, and conflicting national standards shall be withdrawn at the latest by October 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7439:2015.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

## Endorsement notice

The text of ISO 7439:2023 has been approved by CEN as EN ISO 7439:2023 without any modification.

# Contents

Page

Foreword.....	v
Introduction.....	vi
<b>1 Scope.....</b>	<b>1</b>
<b>2 Normative references.....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>1</b>
<b>4 Quality verification.....</b>	<b>2</b>
<b>5 Intended clinical performance.....</b>	<b>3</b>
5.1 General.....	3
5.2 Clinical performance.....	3
5.2.1 General.....	3
5.2.2 Study duration.....	3
5.2.3 Study population.....	3
5.2.4 Sample size.....	4
5.2.5 Contraceptive performance.....	4
5.2.6 Expulsion rate.....	4
5.2.7 Discontinuation rate.....	4
5.2.8 Investigation report.....	4
5.2.9 Labelling.....	5
<b>6 Design attributes.....</b>	<b>5</b>
6.1 General.....	5
6.2 Shape.....	6
6.3 Dimensions.....	6
6.3.1 IUD.....	6
6.3.2 Copper components.....	6
6.3.3 Thread.....	6
6.3.4 Insertion instrument.....	6
6.4 Tensile force.....	6
6.5 Stability.....	7
6.5.1 Shelf-life stability.....	7
6.6 Viscoelastic property.....	7
6.7 Detection by X-ray.....	7
<b>7 Materials.....</b>	<b>7</b>
<b>8 Design evaluation.....</b>	<b>7</b>
8.1 General.....	7
8.2 Determination of dimensions.....	8
8.3 Determination of tensile force.....	8
8.3.1 Principle.....	8
8.3.2 Apparatus.....	8
8.3.3 Procedure.....	8
8.3.4 Test report.....	8
8.4 Test of elastic recovery (memory test).....	9
8.4.1 Principle.....	9
8.4.2 Procedure.....	9
8.4.3 Test report.....	9
8.5 Determination of barium sulfate content and identification of barium and sulfate.....	9
8.5.1 Ash content test.....	9
8.5.2 Identity test.....	9
8.6 Pre-clinical evaluation.....	9
<b>9 Manufacturing and inspection.....</b>	<b>10</b>
<b>10 Sterilization.....</b>	<b>10</b>

<b>11</b>	<b>Packaging</b> .....	<b>10</b>
<b>12</b>	<b>Information to be supplied by the manufacturer</b> .....	<b>10</b>
12.1	General.....	10
12.2	Labelling of the primary container.....	11
12.3	Labelling of the secondary container.....	11
12.4	Instructions for the health care providers.....	11
12.5	Information intended for the client after insertion of the IUD.....	12
12.6	Written information intended for the client.....	13
<b>Annex A (normative) Sampling requirements for testing copper bearing IUDs</b> .....		<b>14</b>
<b>Bibliography</b> .....		<b>16</b>

Preview document is a preview generated by EVS

## 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.

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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 7439:2015), which has been technically revised.

The main changes are as follows:

- the subclause on clinical performance has been revised (see [5.2](#));
- the movable collar has been added in the subclause on insertion instrument (see [6.3.4](#));
- requirements for packaging integrity have been added;
- the instructions for health care providers have been amended in accordance with the "Family planning: A global handbook for providers"<sup>[4]</sup>;
- the requirement for stability in situ has been removed since there is no practical way of controlling it.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## 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.

The IUD is a highly effective contraceptive device with a long history of safe use. It can be used for many years, with a prompt return of fertility upon removal.

IUDs do not prevent sexually transmitted infections and condom use is recommended for those at risk.

IUDs containing copper are regarded as single use sterile medical devices implanted in the uterus. These medical devices are inserted and removed by trained and competent health care providers.

# Copper-bearing contraceptive intrauterine devices — Requirements and tests

## 1 Scope

This document 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 or other medicinal products.

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

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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 information to be supplied by the manufacturer — Part 1: General requirements*

ASTM D 3078, *Standard test method for determination of leaks in flexible packaging by bubble emission*

ASTM F 1929, *Standard test method for detecting seal leaks in porous medical packaging by dye penetration*

European Pharmacopoeia, (Ph. Eur.)<sup>1)</sup>

## 3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

### 3.1

#### contraceptive intrauterine device

#### IUD

copper-bearing device placed in the uterine cavity for the purpose of preventing pregnancy

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