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

Dispositifs intra-utérins contenant du cuivre — Spécifications, essais

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO 7439:2002](https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-b3d88c65f46a/iso-7439-2002)

[https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-
b3d88c65f46a/iso-7439-2002](https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-b3d88c65f46a/iso-7439-2002)



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO 7439:2002](#)

<https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-b3d88c65f46a/iso-7439-2002>

© ISO 2002

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

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.ch
Web www.iso.ch

Printed in Switzerland

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.

Contents

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Intended performance	2
5 Design attributes	2
6 Materials	3
7 Design evaluation	3
8 Manufacturing and inspection	7
9 Sterilization	7
10 Packaging	7
11 Information supplied by the manufacturer	7
Annex ZZ Corresponding International and European Standards for which equivalents are not given in the text	10
Bibliography	11

ITeH STANDARD PREVIEW
(standards.iteh.ai)
<https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-b3d88c65f46a/iso-7439-2002>

Foreword

This document (EN ISO 7439:2002) has been prepared by Technical Committee CEN/TC 285 "Non-active surgical implants", the secretariat of which is held by NEN in collaboration with Technical Committee ISO/TC 157 "Mechanical contraceptives".

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 September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.

This European Standard needs to be considered in conjunction with EN ISO 14630, which contains requirements that apply to all non-active surgical implants. Although contraceptive intra-uterine devices are not *surgical* implants, most of the requirements of EN ISO 14630 may be applicable to contraceptive intra-uterine devices.

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(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard : Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO 7439:2002](https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-b3d88c65f46a/iso-7439-2002)

<https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-b3d88c65f46a/iso-7439-2002>

Introduction

Although every *foreign* object in the uterus exhibits a certain contraceptive effect, the method by which copper-bearing intra-uterine contraceptive devices (IUDs) function is by the continuous release of copper ions. This interferes with some enzymatic functions, immobilizes sperm cells and inhibits fertilization. In addition, growth and development of the ovum, tubal function and implantation are inhibited and the biochemical environment of the uterus is altered. These contribute to the high effectiveness of contraception.

The effectiveness of copper-bearing contraceptive intra-uterine devices is many times greater than that of a simple plastics body.

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

Contraceptive intra-uterine devices whose primary purpose is to release progestogens are regulated as medicinal products and are subject to 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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO 7439:2002](https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-b3d88c65f46a/iso-7439-2002)

<https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-b3d88c65f46a/iso-7439-2002>

1 Scope

This European Standard applies to single-use copper-bearing intra-uterine contraceptive devices and their insertion instruments. Intra-uterine contraceptive devices consisting only of a plastics body and intra-uterine contraceptive devices whose primary purpose is to release progestogens are not included in the scope of this standard.

NOTE Some aspects of this standard can be applicable to medicated intra-uterine devices and intra-uterine devices that do not contain copper.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of, any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 540, Clinical investigation of medical devices for human subjects.

EN 980, Graphical symbols for use in the labelling of medical devices.

EN 1441, Medical devices – Risk analysis.

EN ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing (ISO 10993-1 : 1997).

EN ISO 14630 : 1997, Non-active surgical implants – General requirements (ISO 14630: 1997).

European Pharmacopoeia.

ITEH STANDARD PREVIEW
(standards.iteh.ai)

3 Terms and definitions

ISO 7439:2002

[https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-](https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-48806540a430/iso-7439-2002)

For the purposes of this standard, the following terms and definitions apply:

3.1

intra-uterine contraceptive device

IUD

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

3.2

insertion instrument

instrument designed to place an IUD in the uterine cavity

3.3

thread

attachment to an IUD for the purpose of verifying the presence of and enabling the removal of the IUD

NOTE The thread is intended to lie in the cervical canal and the vagina when the body of the device is placed correctly in the uterine cavity.

3.4

visco-elastic property

property of an IUD enabling an approximate return to their initial configuration after deformation

3.5

active surface area

surface area of copper in the IUD that is intended to come into contact with uterine fluids

4 Intended performance

4.1 General

The requirements of clause 4 of EN ISO 14630:1997 shall apply.

4.2 Clinical performance

For physical requirements see clause 5.

An IUD shall meet the following requirements for a period of 3 years (the minimum intended lifetime of use):

- pregnancy rate ≤ 2 per 100 woman years during the 1st year as calculated by life-table analysis;
- expulsion rate < 10 per 100 woman years during the 1st year as calculated by life-table analysis.

5 Design attributes

5.1 General

The requirements of clause 5 of EN ISO 14630:1997 shall apply.

Thread and copper shall be integral parts of the IUD.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

5.2 Shape

When tested by visual and tactile inspection an IUD shall have a form fitting the uterine cavity and designed in such a way as to minimize the risk of perforation and subsequent bowel obstruction. The IUDs and insertion instruments shall not exhibit sharp edges.

<https://standards.iteh.ai/catalog/standards/sist/a8db72b1-9898-4edf-b024-b3d88c65f46a/iso-7439-2002>

The design of the IUD shall be such that no excessive forces are required for insertion and removal.

5.3 Dimensions

5.3.1 IUD

The nominal length of an IUD shall not be greater than 36 mm, the nominal width of an IUD shall not be greater than 32 mm.

When determined as specified in 7.2.1, the dimensions shall be consistent with the specifications as given by the manufacturer within tolerances of $\pm 5\%$.

5.3.2 Copper components

The nominal active surface area of copper shall be at least 200 mm^2 , but shall not be larger than 380 mm^2 . If copper wire is used, the nominal diameter of the copper wire shall be at least 0,25 mm.

The diameter shall be consistent with the specifications as given by the manufacturer within tolerances of $\pm 5\%$ and the active surface area within tolerances of $\pm 10\%$.

5.3.3 Thread

When determined in accordance with 7.2.2 the length of the thread shall be not less than 100 mm.

5.3.4 Insertion instrument

The maximum nominal outer width of the part of an insertion instrument intended to come into contact with the cervical canal shall not be greater than 5 mm.

The dimensions shall be consistent with the specifications as given by the manufacturer within tolerances of $\pm 5\%$.

5.4 Tensile force

When tested in accordance with 7.3 the IUD, including the thread, shall withstand a tensile force of at least 12 N.

5.5 Stability

5.5.1 Shelf-life stability

The IUD shall meet any performance specification given by the manufacturer for the complete duration of the declared shelf-life.

5.5.2 In situ stability

During its intended period of use the copper components shall retain structural integrity and the entire IUD shall withstand the tensile force according to 5.4.

5.6 Visco-elastic property

When tested in accordance with 7.4 the recovery of any part of the IUD from its original design position shall be such that the residual deformation does not exceed 5 mm.

5.7 In situ detection

All parts of the IUD frame shall be detectable by X-ray examinations. If barium sulphate is used in the plastics components as the opaque material its content shall range from 15% (w/w) to 25% (w/w), when tested as specified in 7.5.

6 Materials

The requirements of clause 6 of EN ISO 14630:1997 shall apply.

The plastics body including the substance conferring radio-opacity shall be visco-elastic, biocompatible and non-absorbable.

The thread shall be monofilament, biocompatible and non-absorbable.

The purity of the copper shall be at least 99,9% which shall be certified.

7 Design evaluation

7.1 General

The requirements of 7.1 of EN ISO 14630:1997 shall apply.

7.2 Determination of dimensions

7.2.1 For determining the dimensions of the IUD and the outer diameter of the insertion instrument a method that does not alter the shape, e.g. a contour analyzer or any other instrument providing similar accurate results, shall be used.