SLOVENSKI STANDARD
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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)

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

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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 Management Centre has the same status as the official versions.

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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of an identical text or by endorsement, at the latest by September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.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).

For relationship with EU Directive(s), 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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.

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.

3 Terms and definitions

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 $\leq$ 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.

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.

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 ± 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 ± 5 % and the active surface area within tolerances of ± 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 ± 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.

7.2.2 For determining the length of the thread a ruler or any other instrument providing similar accurate results shall be used.

7.2.3 The active surface area shall be computed using mathematical formulas.

7.3 Determination of tensile force

7.3.1 Principle

The IUD including the thread is stretched until breakage of the IUD or detachment or breakage of the thread occurs. The force required to cause breakage is measured.

7.3.2 Apparatus

Tensile testing machine capable of a substantially constant rate of traverse and complying with the following requirements:

a) a force range of 0 N to 100 N;

b) a separation speed of (3,3 ± 0,3) mm/s or (200 ± 20) mm/min;

c) automatic recording of force applied during test; a chart recorder may be used.

7.3.3 Procedure

The test method shall be designed in such a way that the potentially weakest part of the IUD is exposed to the tensile force.

The IUD shall be conditioned at a temperature of (23 ± 2) °C and relative humidity of (50 ± 5) % for at least 24 h. Each IUD is placed into the tensile testing machine according to the manufacturer's instructions. If no instructions are supplied by the manufacturer, the upper part of the IUD is placed in the upper clamp with thread(s) placed in the lower clamp at a distance of 5 cm from its point of attachment to the IUD. Force is then applied and the IUD is stretched until either it or the thread breaks or detaches. The force at break or detachment is measured and recorded.

7.3.4 Test report

The test report shall include the following:

a) identification of the sample;

b) number of IUDs tested;

c) breaking force, in newtons, of each IUD;

d) position of the break;

e) date of testing.