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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.

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)]

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

3.2
insertion instrument
instrument designed to place an IUD in the uterine cavity

3.3
thread
attachment to an IUD for the purposes of verifying the presence and enabling the removal of the IUD

Note 1 to entry: 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.

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

3.4
visco-elastic property
property of an IUD enabling an approximate return to its 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

ISO 14630:2012, Clause 4, shall apply.

4.2 Clinical performance

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

— the upper limit of the 95 % confidence level, two-sided confidence interval for the one-year pregnancy rate computed using life table methods shall be ≤ 2 %;

— one-year expulsion rates computed using life table methods shall be ≤ 10 %;

— one-year discontinuation rates computed using life table methods shall be ≤ 35 %.

5 Design attributes

5.1 General

ISO 14630:2012, Clause 5, 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 IUD 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 be ≤ 36,2 mm; the nominal width of an IUD shall be ≤ 32,3 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 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 that 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 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 as given in Table 1.

Table 1 — Tensile force of IUDs

IUD type	Tensile force N
T-shaped devices	9,5
All other devices	12

5.5 Stability

5.5.1 Shelf-life stability

The IUD shall meet any performance specification given by the manufacturer based on *in vitro* studies for the complete duration of the declared shelf life.

5.5.2 *In situ* stability

During the length of the intended period of use, the frame, together with copper components, shall retain structural integrity and the entire IUD shall withstand the tensile force in accordance with 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 examination. If barium sulfate is used in the plastics components as the opaque material, its content shall range from 15 % (mass fraction) to 25 % (mass fraction), when tested in accordance with 7.5.

6 Materials

ISO 14630:2012, Clause 6, shall apply.

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