SLOVENSKI STANDARD
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Intrauterini kontracepcijski pripomočki z bakrenim nosilcem - Zahteve in preskusi (ISO/DIS 7439:2022)

Copper-bearing contraceptive intrauterine devices - Requirements and tests (ISO/DIS 7439:2022)

Kupferhaltige Intrauterinpessare zur Empfängnisverhütung – Anforderungen und Prüfungen (ISO/DIS 7439:2022)

Dispositifs contraceptifs intra-utérins contenant du cuivre - Exigences et essais (ISO/DIS 7439:2022)

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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 forth edition cancels and replaces the third edition (ISO 7439:2015).

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 Cu-IUD is highly effective in the prevention of pregnancy. While in place in the uterus, its effectiveness can last up to 12 years with no delay in the return of fertility once removed.*[1)]

Copper-bearing intrauterine devices do not prevent sexually transmitted infections and condom use is recommended for those at risk.

The effectiveness of copper-bearing IUDs is many times greater than that of a simple plastics body, with duration of use up to 12 years.

Contraceptive IUDs containing copper are regarded as single use sterile medical devices implanted in the uterus. These medical devices must be inserted by trained and competent Health Care Providers.

1) Less than 1 pregnancy per 100 women using an IUD over the first year (6 per 1,000 women who use the IUD perfectly, and 8 per 1,000 women as commonly used). This means that 992 to 994 of every 1,000 women using IUDs will not become pregnant.

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 or other medicinal products.

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 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

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

European Pharmacopoeia, (Ph. Eur.)[2)]

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*

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

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

3.3
thread
a retrieval string attached 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.

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

3.6
lot
definite amount of IUDs produced during essentially the same time using the same process, same lots of raw materials, common equipment and be sterilized at the same time

3.7
client
user or recipient or patient receiving a contraceptive product

3.8
UDI (Unique Device Identifier)
series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard.

Note 1 to entry: The unique identifier may include information on the lot or serial number and be able to be applied anywhere in the world. It allows the unambiguous identification of a specific medical device.

4 Quality verification

Copper bearing IUDs should be manufactured within an integrated quality management system conforming to ISO 13485, Medical devices — Quality management systems — Requirements for regulatory purposes for the manufacture of medical devices. For most countries and regions this is a regulatory requirement.

For quality verification purposes, the sample size requirements and acceptance criteria specified in Annex A shall be used. These requirements are based on ISO 2859-1, Sampling procedures for inspection by attributes Part 1, Specification for sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection.

The sampling plans have been simplified to take into account typical industry lot sizes, the specific characteristics of IUDs and the nature of the manufacturing processes used to produce them. The sample sizes and acceptance criteria have been selected to provide an acceptable level of consumer protection taking into account the costs of sampling and testing. In addition to verification testing, it is strongly recommended that manufacturers conduct process validation and capability studies, and adopt statistical process control procedures such as the use of control charts to ensure acceptable product quality.

The sampling and acceptance criteria given in Annex A are intended to cover the following situations:

a) Continuing production of lots within a stable manufacturing environment.

b) The assessment of isolated lots (e.g. fewer than 5) for example when purchasers may wish to conduct confirmatory testing on a limited number of lots, when production is interrupted or intermittent, or for surveillance testing.

In addition, the rules for switching between normal and tightened inspection in ISO 2859 have been adopted to provide greater level of consumer protection should the quality of a manufacturing process deteriorate. These rules are applied as follows:

Normal Inspection –the specified sample sizes for normal inspection apply at the start of production. Normal inspection continues to apply unless two nonconforming lots are found in any sequence of 5 or fewer lots tested. If this occurs the number of samples used to assess the conformity for future lots shall be increased to those specified for tightened inspection.

Tightened Inspection – the specified sample sizes for tightened inspection shall apply until a sequence of 5 lots have been accepted. Following the acceptance of 5 sequential lots, the manufacturer may return to the sample sizes for normal inspection.

The switch to reduced inspection has not been adopted for the testing of copper bearing IUDs. Switching to smaller sample sizes is not considered acceptable given the potential for increased consumer risk because of the small sample sizes specified under normal inspection for many of the tests.

5 Intended clinical performance

5.1 General

ISO 14630:2012, Clause 4, shall apply.

ISO 14155:2020 shall apply.

5.2 Clinical performance

An IUD shall meet the following requirements, based on a single-arm clinical study over a period of five years of user wear-time (the minimum intended lifetime of use). The manufacturer shall present these data in a Final Report of the clinical evaluation before releasing a modified or newly designed IUD onto the market.

NOTE Guidance conducting a clinical study of Cu-IUDs is provided in ISO 11249, Copper-bearing intrauterine contraceptive devices — Guidance on the design, execution, analysis and interpretation of clinical studies.

IUD and IUD insertion instrument

The IUD and IUD insertion instrument shall be carefully designed to work together. The clinical study design shall ensure that the insertion instrument used in the study is the same (or very similar) instrument that is marketed with or for the IUD.

NOTE Clinical validation for minor changes that don't effect the safety and effectiveness of the insertion device may not be necessary. Significant changes that might effect the safety and effectiveness may require a new clinical validation.

5.2.1 Study Duration

The clinical study duration must be a minimum of five years, i.e. follow study subjects for a minimum of five years of user wear-time. The duration must be as long as the proposed duration of use for the IUD labelling.

5.2.2 Study Population

The clinical study population must comprise women who are at risk for pregnancy, i.e. women who have regular unprotected heterosexual vaginal intercourse.