

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

The European Standard EN ISO 7439:2002 has the status of a British Standard

ICS 11.200

National foreword

This British Standard is the official English language version of EN ISO 7439:2002. It is identical with ISO 7439:2002.

The UK participation in its preparation was entrusted to Technical Committee CH/30, Mechanical contraceptives, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 4 April 2002

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essais (ISO 7439:2002)

Kupferhaltige Intrauterinpressare zur Empfängnisverhütung
- Anforderungen, Prüfungen (ISO 7439:2002)

This European Standard was approved by CEN on 20 April 2001.

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of an identical text or by endorsement, at the latest by September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.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