FINAL
DRAFT

AMENDMENT

ISO 7439:2002 FDAM 1

ISO/TC **157**

Secretariat: **DSM**

Voting begins on:
2009-03-12

Voting terminates on:
2009-05-12

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

AMENDMENT 1

Dispositifs intra-utérins contenant du cuivre — Exigences, essais —
AMENDEMENT 1

Please see the administrative notes on page iii

Reference number
ISO 7439:2002/FDAM 1:2009(E)

ISO/CEN PARALLEL PROCESSING

This final draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 7439:2002 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

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

AMENDMENT 1

Page iii, Foreword

Delete the last three paragraphs.

Page vi, Introduction, first paragraph

Delete the third sentence:

> In addition, growth and development of the ovum, tubal function and implantation are inhibited and the biochemical environment of the uterus is altered.

Page vi, Introduction

Add the following sentence immediately after the last paragraph:

> It is advisable that significant changes in the design of the IUD, insertion device, specification or insertion technique be validated.

Page 1, Normative references

Replace the list of normative references with the following:

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 14630:2008, *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

Throughout the text replace EN 540 with ISO 14155-1, EN 1441 with ISO 14971, EN 980 with ISO 15223-1, EN ISO 14630 with ISO 14630 and EN ISO 10993-1 with ISO 10993-1.

Page 2, 4.2 Clinical performance

Replace the contents of this subclause with the following:

An IUD shall meet the following requirements for a period of 5 y (the minimum intended life time 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 $\leqslant$ 2 %;

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

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

Page 2, 5.3.1 IUD

Replace the first paragraph with the following:

The nominal length of an IUD shall be $\leqslant$ 36,2 mm; the nominal width of an IUD shall be $\leqslant$ 32,3 mm.

Page 3, 5.4 Tensile force

Replace the existing text with the following:

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

Page 3, 5.5.1 Shelf-life stability

The sentence shall read as:

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.

Page 3, 5.5.2 In situ stability

The sentence shall read as:

During the length of intended period of use, the frame together with copper components shall retain structural integrity and the entire IUD shall withstand the tensile force according to 5.4.

Page 5, 7.4.2 Procedure

Add the following after 7.4.2 a) as a note:

NOTE T-shaped devices are usually inserted into a tube with an inner diameter of 3 mm to 10 mm.

Page 6, 7.7 Clinical evaluation, first paragraph

Replace the whole of the first paragraph, including the first unnumbered list, with the following:

Before releasing modified or newly designed IUDs on to the market the manufacturer shall present clinical evaluation in accordance with the following requirements.

Contraceptive efficacy rates shall be determined in a randomized controlled equivalence or non-inferiority trial using TCu380A, if possible, as the control device. If not, another IUD with a well established pregnancy rate shall be used. Appropriate sample sizes shall be used to ensure that the pregnancy rate criterion specified in 4.2 can be met. Any trial shall include at least 20 000 women-months for the device under test.

Compliance with this International Standard can be demonstrated by conducting a randomized study in which an average of 720 women use the test device in the first year of the study and an average of 360 women in a control arm use the TCu380A device if possible. If not, another IUD with a well established pregnancy rate shall be used.

NOTE 1 A study with an average of 720 women followed during the first year of use and a true pregnancy rate of 1 % would have an approximate 95 %-level, two-sided confidence interval for the first year pregnancy rate of (0,4 % to 2,0 %). Depending on the attrition rate in the study cohort, this could be achieved by enrolling between 900 women and 1 000 women.

The control arm using TCu380A shall be included in the trial to confirm that no bias is introduced due to the study methodology and/or the population using the index device. This can be demonstrated if an average of 360 women are followed during the first year of use.

NOTE 2 Assuming a true pregnancy rate of 1 % for TCu380A, the approximate 95 %-level, two-sided confidence interval for the first year pregnancy rate would be (0,2 % to 2,7 %). Depending on the attrition rate in the study cohort, this could be achieved by enrolling between 450 women and 500 women. Hence the upper limit of the 95 %, two-sided confidence interval for the TCu380A should be no greater than 2,7 %.

NOTE 3 A randomized controlled study designed as an equivalence trial with an average number of women of 720 and 360 women in each arm would declare as equivalent two devices with true pregnancy rates of 1 % equivalent if the difference in observed pregnancy rates was $\leqslant$ 2,1 %. Therefore, a study of this size will have very limited significance.

The clinical investigation shall be performed in accordance with ISO 14155-1.

Page 7, 7.7 Clinical evaluation, last paragraph

Replace item 3 of the last unnumbered list with the following:

— clinical follow up frequency;

(i.e., delete *and instruction for "self-check"*).

Page 7,11.2 Labelling on the primary container

Item 5 of the list shall read:

— before expiry date;

Add the following item at the end of the list:

— the maximum life time *in situ*.

Page 8, 11.4 Instructions for use

Delete item 14 from the list:

— slightly increased risk of perforation when an IUD is inserted in a woman who is fully breast feeding;

Page 10, Annex ZZ

Delete Annex ZZ.

Annex ZA
(informative)

Relationship between this Amendment and the Essential Requirements of EU Directive 93/42

By agreement between ISO and CEN, this CEN annex is included in the DAM and the FDAM but will not appear in the published ISO Amendment.

This Amendment pertains to ISO 7439:2002, which was prepared under a mandate given to CEN by the European Commission to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42.