



DRAFT AMENDMENT ISO 7439:2002/DAmD 1

ISO/TC 157

Secretariat: **DSM**

Voting begins on:
2003-09-11

Voting terminates on:
2004-02-11

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

AMENDMENT 1

Dispositifs intra-utérins contenant du cuivre — Exigences, essais

AMENDEMENT 1

ICS 11.200

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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.

Amendment 1 to ISO 7439:2001 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

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Requirements regarding maximum acceptable pregnancy rate

p. 3, Introduction

Delete the sentence: *“In addition, growth and development of the ovum, tubal function and implantation are inhibited, and the biochemical environment of the uterus is altered.”*

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p. 5, 4. Intended performance, 4.2 Clinical performance

Replace the value “2” by the value “1”, to read as follows:

“ - pregnancy rate ≤ 1 per 100 woman years during the first year, as calculated by life table analysis”.