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AMENDMENT 1
2012-02-15

Mechanical contraceptives — Reusable natural and silicone rubber contraceptive diaphragms — Requirements and tests

AMENDMENT 1

Contraceptifs mécaniques — Diaphragmes contraceptifs réutilisables en caoutchouc — Performances et essais

AMENDEMENT 1

Reference number
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Foreword

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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.

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 8009:2004 was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

Mechanical contraceptives — Reusable natural and silicone rubber contraceptive diaphragms — Requirements and tests

AMENDMENT 1

Page 1, Clause 2

Add the following reference:

> ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

Page 2, Clause 6

Replace the second, third and fourth paragraphs with the following:

> For any new product, or following a significant change to the formulation or manufacturing process, biocompatibility assessments shall be conducted in accordance with ISO 10993-1. Testing for cytotoxicity in accordance with ISO 10993-5, and for irritation and sensitization in accordance with ISO 10993-10, shall be conducted. Spermicides applied at the time of use are exempt from this requirement. Where practicable, manufacturers should take steps to recommend spermicides that minimize irritant effects. Accredited laboratories shall be used for all biocompatibility testing. Regulatory bodies might also specify local requirements and require results to be interpreted by a qualified toxicologist. Any toxicologist's assessment report shall state that the product is safe under normal conditions of use.

Page 26, Bibliography

Delete ISO 10993-1 from the list.

Renumber the subsequent references accordingly.

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Price based on 1 page