INTERNATIONAL STANDARD

ISO 8009

Second edition
2014-11-15

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

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

Reference number
ISO 8009:2014(E)

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Published in Switzerland

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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.

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 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 second edition cancels and replaces the first edition, ISO 8009:2004, of which it constitutes a minor revision. It also incorporates the amendment ISO 8009:2004/Amd1:2012.

Introduction

Diaphragms are medical devices, therefore, they should be produced under a good quality management system. Reference should be made, for example to the ISO 9000- series, in conjunction with ISO 13485.

The sampling plans and acceptance quality limits (AQLs) given in this International Standard are for referee testing. The AQLs represent the maximum tolerable level of defects in the products. As diaphragms are intended for re-use, manufacturers should strive for entirely defect-free product.

Manufacturers can devise and apply additional and alternative quality control measures for their use and after production. These methods can differ among manufacturers.

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

1 Scope

This International Standard specifies the minimum requirements and test methods to be used for reusable diaphragms made from natural rubber and silicone rubber. These diaphragms are intended for contraceptive use.

This International Standard is not applicable to other vaginal contraceptive barriers, such as those known as cervical caps, vaginal sponges, and vaginal sheaths.

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 188, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

ISO 463, *Geometrical Product Specifications (GPS) — Dimensional measuring equipment — Design and metrological characteristics of mechanical dial gauges*

ISO 2859-1:1999, *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 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

3 Terms and definitions

For the purpose of this document, the terms and definitions given in ISO 2859-1 and the following apply.

3.1
lot
batch
collection of diaphragms of the same design, colour, shape, size, and formulation, manufactured at essentially the same time, using the same process, common lots of raw materials, common equipment and personnel

Note 1 to entry: The size of a lot is not specified in this International Standard, but it can be specified by a purchaser as part of a purchasing contract. Depending on the method of manufacture, multiple sizes can be produced in a defined lot/batch. In such cases, traceability can be maintained by using both the lot number and the size.