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

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

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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.

4 Sampling

Sampling and establishment of the sampling plan shall be carried out as described in ISO 2859-1.

NOTE It is necessary to know the lot size in order to derive from ISO 2859-1 the number of samples to be tested. The lot size varies among manufacturers, and is regarded as part of the process and quality controls used by the manufacturer.

5 Classification

Diaphragms shall be classified into the following types:

a) **Type 1**: Coil-spring diaphragm, also known as a helically wound diaphragm.

b) **Type 2**: Flat-spring diaphragm, also known as a flat-leaf diaphragm, watch-spring diaphragm, or *Mensinga* diaphragm.

c) **Type 3**: Arcing-spring diaphragm, also known as an arcing-bend diaphragm or bow-bend diaphragm.

6 Materials

The diaphragm, excluding the spring, shall be made of a natural or silicone rubber compound.

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.

NOTE Many latex products that have been established as safe, including diaphragms and medical gloves, can exhibit a positive cytotoxic response when tested according to ISO 10993-5. While any cytotoxic effect can be of concern, it is primarily an indication of potential for *in vivo* toxicity, and a diaphragm cannot necessarily be determined to be unsuitable for use based solely on cytotoxicity data.

7 Design

7.1 General

The diaphragm shall consist of a dome and an integral peripheral rim. The dome of the diaphragm and the portion forming the rim shall be one continuous film.

7.2 Rim

The rim of the diaphragm shall be reinforced with a spring, which shall be sufficiently rigid to hold the rim in a flat, circular configuration.

7.3 Reinforcing spring

The reinforcing spring shall be completely encapsulated and centrally located within the rim.

7.4 Spring ends

The ends of the spring shall be joined in such a manner that the joint does not project through the surface of the rim.

7.5 Dome and rim

The dome and rim shall have a uniform, smooth, and non-tacky finish.

8 Dimensions

8.1 Diameter

The nominal diameters of preferred sizes shall be 55 mm, 60 mm, 65 mm, 70 mm, 75 mm, 80 mm, 85 mm, 90 mm, 95 mm, and 100 mm.

When tested in accordance with Annex A, the two diameter measurements shall not differ by more than 4 % of the nominal size. The mean of these two measurements, called diaphragm diameter, shall equal the nominal size within a tolerance of ±2 mm.

Examine 13 diaphragms of each size. No diaphragm diameter shall fall outside the limits.

8.2 Dome thickness

When tested in accordance with Annex B, the thickness of the diaphragm dome at the thinnest point measured shall not be less than 0,20 mm.

9 Tensile properties of the dome

9.1 Tensile strength

When tested in accordance with Annex C, the median tensile strength of 13 diaphragms of each size shall not be less than the values given in Table 1.

When tested in accordance with Annex D, the median tensile strength of 13 oven-treated diaphragms of each size shall not be less than the values given in Table 1.

9.2 Elongation at break

When tested in accordance with Annex C, the median elongation at break of 13 untreated diaphragms of each size shall not be less than the values given in Table 1.

When tested in accordance with Annex D, the median elongation at break of 13 oven-treated diaphragms of each size shall not be less than the values given in Table 1.

Table 1 — Minimum median tensile properties

Property	Natural rubber untreated	Natural rubber oven-treated	Silicone rubber untreated	Silicone rubber oven-treated
Tensile strength, MPa	15	11	7	7
Elongation at break, %	650	500	350	350

10 Mechanical properties of rim and spring — Type 1 and Type 2 diaphragms

10.1 Compression resistance

When 13 diaphragms are tested in accordance with Annex E, during the first and 1 000th compressions the distance between the load points, i.e. resulting from compression, of each diaphragm shall not be lower than 55 % and not greater than 85 % of the original diameter.

After the 1 000th compression, the diameter along the axis of compression shall be at least 90 % of the value measured before the test.

After the 1 000th compression, the rubber film shall show no signs of deterioration when examined by normal or corrected vision.

The degree of twist after 1 000 compressions, measured in accordance with Annex F, shall be not more than 20°.

Manufacturers of diaphragms who are certified to the ISO 9001 quality management system or equivalent, and whose suppliers are similarly certified, may use the repeated compression testing part of this method as a type test. In that case, lot-by-lot testing shall consist of a single compression, and measurement of the compression resistance.

10.2 Twisting during compression

When tested in accordance with Annex F, the diaphragm shall not show an angle of twist greater than 20°.

Each lot shall be sampled in accordance with ISO 2859-1:1999, General inspection level I, but at least according to code letter K.

When tested in accordance with Annex F, the compliance level shall be an AQL of 1,0 %.

11 Freedom from visible defects

When inspected in accordance with Annex G, the diaphragm shall not show any visible defects.

Each lot shall be sampled in accordance with ISO 2859-1:1999, General inspection level I, but at least according to code letter K.

The compliance level shall be an AQL of 0,4 % for the following major defects:

a) hole in the dome;

b) exposed spring;

c) broken spring;

d) distorted shape;

e) illegible marking on the diaphragm;

f) illegible labelling.

For minor defects, when tested in accordance with Annex G, the compliance level shall be an AQL of 1,0 %.

12 Test report

Test reports shall contain at least the information as described in Annex H.

13 Packaging, labelling, and storage

13.1 Packaging

13.1.1 Individual container

Each diaphragm shall be individually packaged in a container designed to protect it from contamination, exposure to light ,and mechanical damage during normal handling, transport, and storage.

The individual container shall be reusable so that it can be used to protect the diaphragm for the term of its useful life.

13.1.2 Outer container(s)

A convenient number of individual containers shall be packed in one or more outer containers which shall be sufficiently robust to protect the contents during transport and storage.

13.2 Labelling

13.2.1 Diaphragm identification

Each diaphragm shall be legibly marked with the following information:

a) the manufacturer's name or recognized trademark;

b) the nominal size, in millimetres.

13.2.2 Individual container identification

The container, as received by the user, shall be legibly marked with the following information:

a) the manufacturer's and/or distributor's name or recognized trademark;

b) the manufacturer's lot number;

c) the nominal size, in millimetres;

d) the manufacturer's recommended last date for supply to the consumer (month and year), i.e. the date after which the diaphragm should not be distributed to consumers. This date shall be no more than two years from the date of manufacture, unless justified by real-time or accelerated test data;

e) the material of which the diaphragm is made.

13.2.3 Instructions

Each individual container shall contain instructions for the use and care of the diaphragm in accordance with Annex I.

13.3 Storage

Rubber tends to deteriorate with age. Diaphragms are packed in a way which normally protects them during storage. Nevertheless, they should not be kept in stock longer than necessary, especially in warm climates. They should be stored in a cool, dry place and should be kept in containers such that the contents will not be subject to mechanical damage or light. As soon as any diaphragm shows deterioration (e.g. tackiness, brittleness, crazing) of the rubber, it should be destroyed.

The diaphragm should not be allowed to come into contact with oil-based antiseptic phenols and their derivatives, petroleum-based grease, petroleum spirit, kerosene, and other related organic products.

Normally it is recommended to destroy test diaphragms after tests are completed. Sometimes diaphragms need to be kept to demonstrate particular problems, thus it is important that these diaphragms be marked or stored in such a way that unintentional use is prevented.