INTERNATIONAL STANDARD

ISO 8009-1

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Reusable rubber contraceptive diaphragms —

Part 1:
Classification, sampling and requirements

Diaphragmes contraceptifs réutilisables en caoutchouc —

Partie 1: Classification, échantillonnage et exigences

Reference number
ISO 8009-1:1997(E)

Contents

Annex

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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.

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.

International Standard ISO 8009-1 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives.*

ISO 8009 consists of the following parts, under the general title *Reusable rubber contraceptive diaphragms:*

- *Part 1: Classification, sampling and requirements*
- *Part 2: Determination of size*
- *Part 3: Determination of dome thickness*
- *Part 4: Freedom from visible defects*
- *Part 5: Determination of tensile properties*
- *Part 6: Determination of deterioration after accelerated ageing*
- *Part 7: Determination of compression resistance of coil spring and flat spring diaphragms*
- *Part 8: Determination of twisting during compression of coil spring and flat spring diaphragms*
- *Part 9: Packaging and labelling*
- *Part 10: Recommendations for storage*

Annex A of this part of ISO 8009 is for information only.

Introduction

The sampling plans and acceptable quality levels (AQLs) given in this part of ISO 8009 are intended for referee testing. Manufacturers may devise and apply other quality control measures during production. These measures will be specific to production methods and plants, and may differ among manufacturers.

The diaphragm, and any lubricant, dressing material or powder applied to it, should neither contain nor liberate substances in amounts that are toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of use. Reference should be made to relevant parts of ISO 10993. A manufacturer may be required by a certification or inspection authority or by a purchaser to provide a certificate of composition and/or other properties.

Reusable rubber contraceptive diaphragms

Part 1:

Classification, sampling and requirements

1 Scope

This part of ISO 8009 gives a classification of, and specifies requirements for, reusable rubber diaphragms (hereafter called diaphragms) supplied in consumer packages for contraceptive use.

This part of ISO 8009 does not cover other vaginal contraceptive barriers, such as those known as cervical caps, vaginal sponges and vaginal sheaths.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8009. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8009 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 2859-1: —[1], *Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection.*
ISO 8009-2:1985, *Reusable rubber contraceptive diaphragms — Part 2: Determination of size.*
ISO 8009-3:1985, *Reusable rubber contraceptive diaphragms — Part 3: Determination of dome thickness.*
ISO 8009-4:1996, *Reusable rubber contraceptive diaphragms — Part 4: Freedom from visible defects.*
ISO 8009-5:1996, *Reusable rubber contraceptive diaphragms — Part 5: Determination of tensile properties.*
ISO 8009-6:1985, *Reusable rubber contraceptive diaphragms — Part 6: Determination of deterioration after accelerated ageing.*
ISO 8009-7:1985, *Reusable rubber contraceptive diaphragms — Part 7: Determination of compression resistance of coil spring and flat spring diaphragms.*
ISO 8009-8:1985, *Reusable rubber contraceptive diaphragms — Part 8: Determination of twisting during compression of coil spring and flat spring diaphragms.*
ISO 8009-9:1985, *Reusable rubber contraceptive diaphragms — Part 9: Packaging and labelling.*
ISO 8009-10:1985, *Reusable rubber contraceptive diaphragms — Part 10: Recommendations for storage.*

3 Definitions

For the purposes of this part of ISO 8009, the definitions given in ISO 2859-1 and the following definition apply.

3.1 lot; batch

Number of diaphragms of the same design, colour, shape, size and latex formulation, manufactured at essentially the same time, using the same process, common lots of raw materials, common equipment and personnel.

NOTE — This part of ISO 8009 does not specify the size of a lot, but it may be possible for a purchaser to do so as part of the purchasing contract.

[1] To be published. (Revision of ISO 2859-1:1989)

4 Sampling

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

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 will vary 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:

Type 1: coil-spring diaphragm, also known as a helically wound diaphragm.

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

Type 3: arcing diaphragm, also known as an arcing-bend diaphragm or bow-bend diaphragm.

6 Materials

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

The diaphragm and any lubricant, dressing material or powder applied to it should neither contain nor liberate substances in amounts that are toxic, sensitizing, locally irritating, or otherwise harmful under normal conditions of use and should not have a deleterious effect on the diaphragm. There should be no adverse reaction between the spring and the material from which the diaphragm is made, and the spring should not be harmful to the user under normal conditions of use.

7 Design

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

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

8 Dimensions

8.1 Diameter

The nominal diameters of preferred sizes are: 45 mm, 50 mm, 55 mm, 60 mm, 65 mm, 70 mm, 75 mm, 80 mm, 85 mm, 90 mm, 95 mm, 100 mm and 105 mm.

When tested in accordance with ISO 8009-2, the two specified measurements shall not differ by more than 4% of the nominal size. The mean of these two measurements 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 8009-3, the thickness of the diaphragm dome at the thinnest point measured shall not be less than 0,20 mm.

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

9 Tensile properties of the rubber dome

9.1 Tensile strength

Examine 13 diaphragms of each size in accordance with ISO 8009-5. The median tensile strength shall not be lower than 20 MPa before oven treatment and 15 MPa after oven treatment in accordance with ISO 8009-6.

9.2 Elongation at break

Examine 13 diaphragms of each size in accordance with ISO 8009-5. The median elongation at break shall not be lower than 700% before oven treatment and 600% after oven treatment in accordance with ISO 8009-6.

10 Mechanical properties of rim and spring in type 1 and type 2 diaphragms

NOTE — This clause does not apply to type 3 diaphragms.

10.1 Compression resistance

When measured in accordance with ISO 8009-7, the distance between the load points of each diaphragm shall not be lower than 55% and not greater than 85% of the original diameter.
Examine 13 diaphragms. Each diaphragm diameter shall show a compression resistance within the range 55 % to 85 % of the original diameter.

10.2 Twisting during compression

When tested in accordance with ISO 8009-8, the diaphragm shall not show an angle of twist greater than 20°.

Each lot shall be sampled in accordance with ISO 2859-1, general inspection level I, but utilizing minimum sample size and corresponding acceptance/rejection number equivalent to sample size code letter K. When tested in accordance with ISO 8009-8, the compliance level shall be an AQL of 1,0%.

If the lot size is less than 125 pieces, all diaphragms shall be tested.

11 Freedom from visible defects

When inspected in accordance with ISO 8009-4, the diaphragm shall not show any visible defects

Each lot shall be sampled in accordance with ISO 2859-1, general inspection level I, but utilizing minimum sample size and corresponding acceptance/rejection number equivalent to sample size code letter K.

For the serious defects:
hole in the dome,
exposed spring,
broken spring,
distorted shape,
illegible marking on the diaphragm and
illegible labelling,
the compliance level shall be an AQL of 0,4%.

For other defects when tested in accordance with ISO 8009-4, the compliance level shall be an AQL of 1,0%.

If the lot size is less than 125 pieces, all diaphragms shall be tested.

12 Packaging and labelling

The diaphragm shall be packaged and labelled as specified in ISO 8009-9.

Examine 13 diaphragms of each size. Each packed diaphragm shall comply with ISO 8009-9.

13 Recommendations for storage

Recommendations for storage are given in ISO 8009-10.

Annex A
(informative)

Bibliography

[1] ISO Guide 7:1994, *Requirements for standards suitable for product certification.*

[2] ISO 2230: —[2], *Vulcanized rubber - Guide to storage.*

[3] ISO 9002:1994, *Quality systems - Model for quality assurance in production and installation.*

[4] ISO 13485:1996, *Quality systems - Medical devices - Particular requirements for the application of ISO 9001.*

[5] ISO 13488:1996, *Quality systems - Medical devices - Particular requirements for the application of ISO 9002.*

[6] ISO 10993 (all parts), *Biological evaluation of medical devices*

[2] To be published. (Revision of ISO 2230:1973)