INTERNATIONAL STANDARD

ISO 8009-4

Second edition
1996-12-15

Reusable rubber contraceptive diaphragms —

Part 4: — Freedom from visible defects

Diaphragmes contraceptifs réutilisables en caoutchouc —

Partie 4: Absence de défauts visibles

Reference number
ISO 8009-4:1996(E)

Contents

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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 8009-4 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

This second edition cancels and replaces the first edition (ISO 8009-4:1985), of which it constitutes a minor revision.

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

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Reusable rubber contraceptive diaphragms —

Part 4:
Freedom from visible defects

1 Scope

This part of ISO 8009 specifies two alternative methods for determining visible defects in reusable rubber contraceptive diaphragms: inspection over a lamp and inspection by inflation. The methods are of equal validity.

2 Principle

Visual inspection of the rim and the distended dome of the diaphragm.

3 Apparatus

3.1 Apparatus for inspection over a lamp, consisting of a transparent cylinder with a light source inside. The cylinder shall not be heated by the light source to the extent that it affects the rubber in the diaphragm. Figure 1 illustrates an example of a suitable apparatus.

3.2 Apparatus for inspection by inflation, consisting of an apparatus that will hold the rim of the diaphragm correctly and maintain the dome in a distended state by air inflation. Figure 2 illustrates an example of suitable apparatus.

4 Procedure

4.1 Inspection over a lamp

Inspect the rim and then pull the diaphragm over the glass cylinder (3.1) so that the rubber is distended about 75% of its maximum distention. Move the diaphragm around and inspect for defects in the dome with normal or corrected vision.

4.2 Inspection by inflation

Inspect the rim and then inflate the diaphragm with air using the apparatus in 3.2 for 1 min so that the rubber is distended about 75% of its maximum distention, and examine the inflated diaphragm for defects in the dome with normal or corrected vision.

5 Test report

The test report shall include the following information:

a) identification of the sample;

b) statement of test method used,

c) number of samples tested;

d) number of diaphragms with one or more of the following visible serious defects: hole in dome, exposed spring, broken spring, distorted shape and illegible labelling;

e) number of diaphragms with one or more of the following visible defects: thin spots in the dome (including the edges), embedded particles, surface tackiness and any other defects likely to affect the serviceability of the diaphragm;

f) date of testing

Dimensions in millimetres

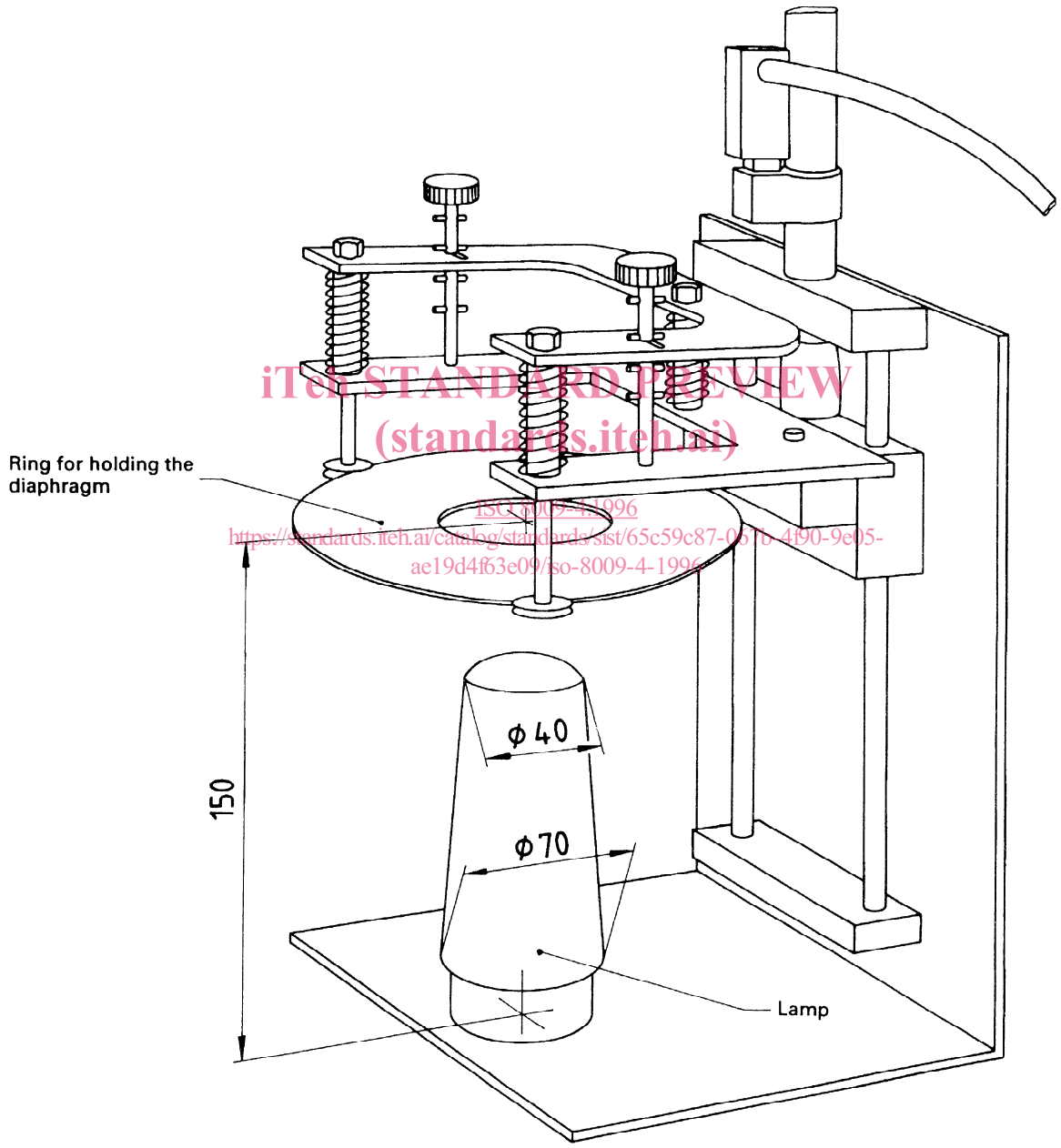

Figure 1 — Example of suitable apparatus for inspection over a lamp

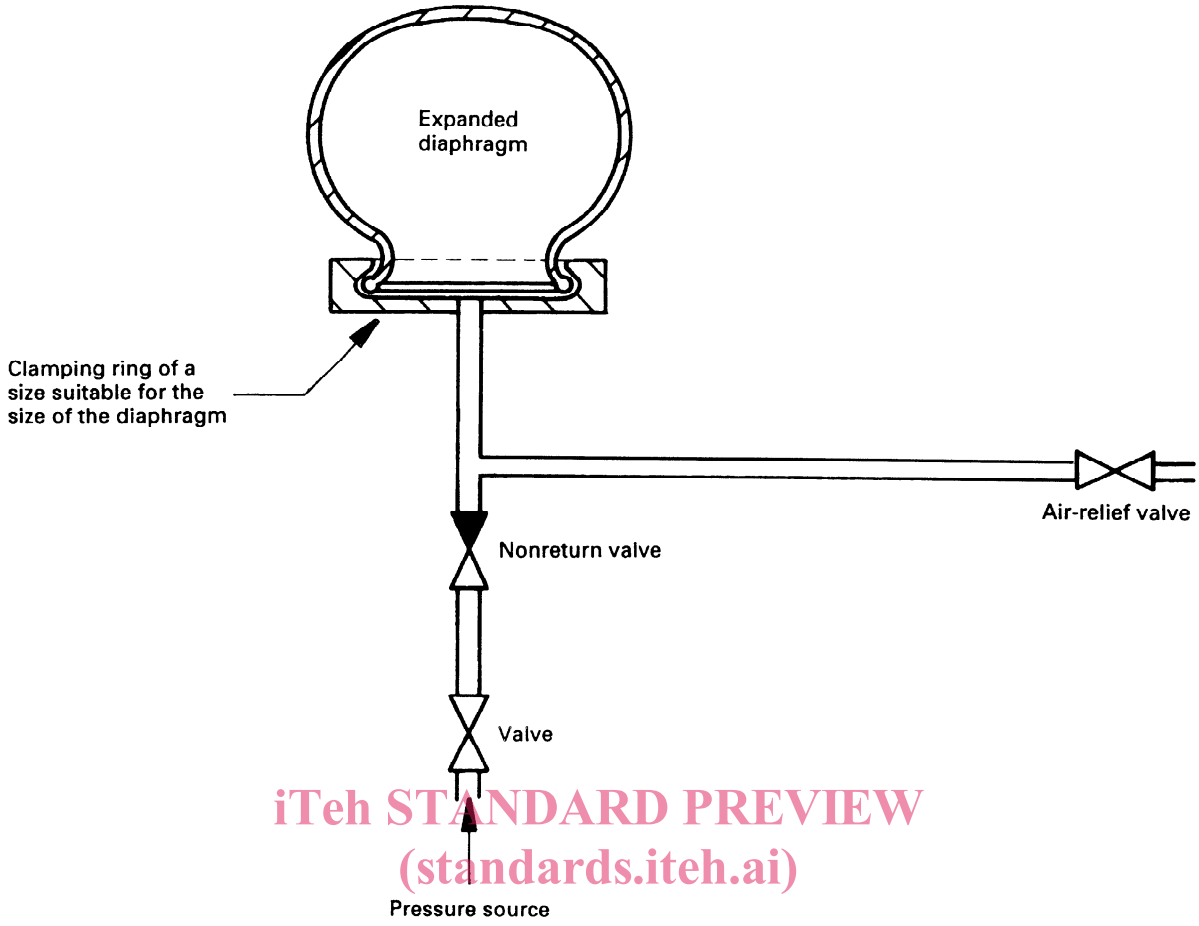

Figure 2 — Example of suitable apparatus for inspection by inflation

ICS 11.200

Descriptors: birth control, contraceptives, contraceptive devices, reusable equipment, caps (contraceptives), tests, detection, defects.

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