
British Standard Specification for

Reusable contraceptive diaphragms

Diaphragmes réutilisables pour la contraception — Spécifications

Wiederverwendbare Diaphragmen für die Empfängnisverhütung

Foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee and is a revision of BS 4028 : 1966 which is withdrawn.

The first edition of BS 4028 was published in 1966 as a result of proposals made by the Family Planning Association. This second edition takes cognizance of, and attempts wherever possible to harmonize with, ISO 8009, currently being prepared by Technical Committee TC 157 Mechanical contraceptives and published by the International Organization for Standardization (ISO).

The major difference in this second edition is the introduction in appendix A of reference sampling plans for assessing manufacturer's claims of conformity. Guidance on sampling for other purposes is introduced as appendix B. The sampling plans are based on the acceptable quality level (AQL) system used to some extent in the draft international standard ISO/DIS 8009 : Part 1 and specified in BS 6001 : Part 1. The sampling plans given in appendices A and B do not apply to third party certification schemes, the sampling plans of which form part of the specific rules for the operation of such schemes.

A further important difference in this second edition is the adoption where possible of the testing methodology given in ISO 8009. The methods given in this standard for the determination of size, dome thickness, compression resistance and twisting during compression are technically equivalent to the corresponding Parts of ISO 8009, whereas the methods for tensile properties, accelerated ageing and visible defects differ. The requirements for packaging and labelling, and the instructions for use and care of diaphragms are based on ISO 8009 : Parts 9 and 10. The relationship between each appendix of this standard and the corresponding Part of ISO 8009 is given in a note in the appendix.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continued surveillance, which may be coupled with assessment of a supplier's quality system against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist users should consider approaching an appropriate body from the list of Association Members.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

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Specification

0 Introduction

Diaphragms are mass-produced articles. Inevitably there will be some variation between individual diaphragms, and a very small proportion of diaphragms may contain defects. Hence, with the exception of the requirements for materials and design given in clauses 3 and 4 respectively, the only feasible way of establishing compliance of diaphragms with the requirements of this standard is by inference from determinations of the properties of a sample of diaphragms taken from a large population.

There are three main purposes of sampling plans in the manufacture and supply of diaphragms, as follows.

- (a) Where a third party certification scheme exists, to establish the rules for sample-taking by a certification body, both from the manufacturer's production line and from the market place, to allow product testing and thereby certification of compliance of the product with the standard as part of the operation of the scheme.
- (b) To inform the manufacturer of the level of sampling that is desirable in order to assure the quality of product necessary to support a manufacturer's declaration of conformity, and to provide a reference method for a bulk purchaser to check such a claim at the time of supply of the consignment.
- (c) To guide on the determination of diaphragm properties for purposes other than checking claims of compliance with the standard, e.g. inspection by a bulk purchaser of stocks of stored diaphragms prior to release for retail supply, or investigation of diaphragms purchased in the market place.

With respect to purpose (a), sampling plans form part of the specific rules of a certification scheme and may vary, depending upon the details of the production plant and whether the samples are drawn for type testing or for production surveillance. In order to allow the necessary flexibility for Certification Bodies to devise specific rules appropriate to each scheme, this British Standard does not specify sampling plans for certification schemes.

With respect to purpose (b) it is acknowledged that a manufacturer will devise and apply quality control measures specific to his production methods and plant and that these measures will differ between manufacturers; sampling plans are therefore not specified in this British Standard. However, unambiguous procedures are necessary to validate claims of compliance with the standard should a dispute arise, and for this reason reference sampling plans and compliance levels are given in appendix A.

With respect to purpose (c) those details of the manufacturing history of the diaphragm (especially batch size) that are necessary for the application of a sampling plan are unlikely to be available to the tester, and therefore have to be assumed. Guidance on sampling plans for this purpose is given in appendix B.

The methods of test in this British Standard are those to be used to determine the various properties of the diaphragm, but are not intended to preclude the use by the manufacturer of methods of equal or better accuracy and repeatability.

1 Scope

This British Standard gives a classification of, and specifies requirements for, reusable diaphragms for contraceptive use, hereinafter called diaphragms.

This standard does not cover other vaginal contraceptive barriers, such as those known as cervical caps, vaginal sponges and vaginal sheaths.

NOTE 1. Reference sampling plans and compliance levels for uses connected with checking manufacturer's declarations of compliance with this British Standard are given in appendix A. This appendix does not apply to third party certification schemes.

NOTE 2. Guidance on the determination of diaphragm properties for purposes other than checking claims of compliance with this British Standard is given in appendix B.

NOTE 3. The titles of the publications referred to in this standard are listed on the inside back cover.

2 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.

3 Materials

The diaphragm, excluding the spring, shall be made of an elastomeric compound and shall be free of discoloration.

NOTE. 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. Lubricants, dressing materials, powders or compounding material should not have a deleterious effect upon 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.

4 Design

4.1 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.

4.2 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.

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

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

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

5 Dimensions

5.1 Diameter

When measured as described in appendix C, the two measurements shall not differ by more than 4 % of the nominal size. The mean external diameter of the diaphragm shall equal the nominal size within a tolerance of ± 2 mm. The per cent non-conforming shall not be greater than 4 %.

NOTE 1. This British Standard does not specify nominal sizes of diaphragm. The usual range of nominal sizes is from 55 mm to 100 mm diameter.

NOTE 2. No sampling plans are specified in this standard (see foreword and introduction), but reference sampling plans for use in cases of dispute over compliance of diaphragms with this standard are given in appendix A.

5.2 Dome thickness

When measured as described in appendix D, the thickness of the diaphragm dome at the thinnest point measured shall not be less than 0.20 mm. The per cent non-conforming shall not be greater than 4 %.

6 Tensile properties of the rubber dome

6.1 Tensile strength

When tested as described in appendix E, the tensile strength of the unaged diaphragm shall be not lower than 12 MPa and the tensile strength of the diaphragm aged as described in appendix F shall be not lower than 10 MPa. The per cent non-conforming shall not be greater than 6.5 %.

6.2 Elongation at break

When tested as described in appendix E, the elongation at break of the unaged diaphragm shall be not lower than 600 % and the elongation at break of the diaphragm aged as described in appendix F shall be not lower than 500 %. The per cent non-conforming shall not be greater than 6.5 %.

7 Mechanical properties of rim and spring in coil spring diaphragms and flat spring diaphragms

NOTE. This clause does not apply to arcing diaphragms.

7.1 Compression resistance

When measured as described in appendix G, the distance between the load points of each diaphragm shall be not lower than 55 % and not greater than 85 % of the original diameter. The per cent non-conforming shall not be greater than 4 %.

7.2 Twisting during compression

When tested as described in appendix H the diaphragm shall not show an angle of twist greater than 20° . The per cent non-conforming shall not be greater than 4 %.

* Marking BS 4028 : 1989 on or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is therefore solely the responsibility of the person making the claim. Such a declaration is not to be confused with third party certification of conformity, which may also be desirable.

8 Freedom from visible defects

When tested for freedom from visible defects as described in appendix J, the per cent non-conforming for critical defects shall not be greater than 0.4 %, the per cent non-conforming for major defects shall not be greater than 1 % and the per cent non-conforming for minor defects shall not be greater than 1 %.

9 Packaging and labelling

9.1 General

The diaphragm shall be packaged and labelled as specified in 9.2 and 9.3.

NOTE. The requirements of clause 9 are based on ISO 8009-9: 1985.

9.2 Packaging

9.2.1 Unit container. Each diaphragm shall be individually packaged in a unit container. The unit container shall contain the instructions for the use and care of the diaphragm (see 9.3.3).

NOTE 1. The unit container should protect the diaphragm from contamination and mechanical damage during normal handling, transport and storage.

NOTE 2. If a marking medium such as ink is used on any part of a package directly in contact with a diaphragm, it should not be deleterious to the diaphragm or harmful to the user.

9.2.2 Outer container. One or more unit containers shall be packaged in an outer container.

NOTE. The outer container should be sufficiently robust to protect the contents during transport and storage.

9.3 Labelling

9.3.1 Diaphragm. The diaphragm shall bear the nominal size, in millimetres. All markings shall be made such that they are not indented in the material of the diaphragm.

NOTE 1. The diaphragm may bear the manufacturer's name or recognized mark.

NOTE 2. If a marking medium such as ink is used on a diaphragm, it should not be deleterious to the diaphragm or harmful to the user.

9.3.2 Unit container. The unit container shall bear at least the following information:

- (a) the manufacturer's and/or distributor's name or recognized mark;
- (b) the manufacturer's lot number;
- (c) the nominal size in millimetres;
- (d) the manufacturer's recommended last distribution date (month and year), i.e. the date after which the diaphragm should not be distributed to consumers;
- (e) the number and year of this British Standard, i.e. BS 4028 : 1989*;
- (f) instructions for storage.

NOTE. See appendix K for guidance on the storage of diaphragms