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Prophylactic dams — Requirements and test methods

Membranes prophylactiques — Exigences et méthodes d'essai

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 29942 was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

Introduction

A prophylactic dam is used to cover parts of the human body during sexual contact. The prophylactic dam (hereinafter also referred to as “dam”) provides coverage to the external female genitalia or the anal area. Non-porous, intact, polymer films have been demonstrated as barriers to the human immunodeficiency virus (HIV) and other infectious agents responsible for the transmission of sexually transmitted infections (STIs). To be effective, it is essential that dams be free from holes and defects, have adequate physical properties so as not to break during use, be correctly packaged to protect them during storage and be correctly labelled to facilitate their use.

To be safe, it is essential that the dam and additive, dressing, individual packaging material or powder applied to it neither contain nor liberate substances in amounts that are toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of storage or use.

Prophylactic dams are non-sterile medical devices; however, a clean environment is essential to minimize microbiological and particulate contamination of the product during manufacturing and packaging. To ensure a high-quality product, it is essential that it be designed and produced under a good quality management system. See ISO 13485 and ISO 14971 for more details on risk management and quality management.

It is intended that manufacturers conduct stability tests to estimate the shelf-life of any new or modified design before the product is placed on the market. These tests are intended to ensure that manufacturers have adequate data to support shelf-life claims before products are placed on the market and that these data are available for review by regulatory authorities, test laboratories and purchasers. They are also intended to limit the need for third parties to conduct long-term stability studies. Real-time shelf-life studies are also initiated, but not necessarily completed, prior to placing the product on the market.

Prophylactic dams — Requirements and test methods

1 Scope

This International Standard specifies the minimum requirements and test methods for prophylactic dams used to assist in the prevention of sexually transmitted infections.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 34-1, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

ISO 37, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

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

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 4074, *Natural latex rubber condoms — Requirements and test methods*

ISO/TR 8550-1, *Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 1: Acceptance sampling*

ISO/TR 8550-2, *Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 2: Sampling by attributes*

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*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223 (all parts), *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

3 Terms and definitions

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

3.1
acceptance quality limit
AQL
quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling

[ISO 2859-1:1999, definition 3.1.26]

3.2
consumer package
package intended for distribution to a consumer, containing one or more individual containers of prophylactic dams

3.3
date of manufacture
date of formation of the prophylactic dam

3.4
expiry date
date after which the prophylactic dam cannot be used

3.5
prophylactic dam
piece of polymer film that prevents the transmission of micro-organisms, which can cause sexually transmitted infections, and is designed to cover the anal area and/or the external female genitalia

3.6
identification number
number, or combination of numerals, symbols or letters used by a manufacturer on consumer packages to uniquely identify the lot numbers of individual prophylactic dams contained in that package, and from which it is possible to trace those lots through all stages of manufacturing, packaging and distribution

NOTE Whenever the consumer package contains only one kind of prophylactic dam, the identification number can be the same as the lot number. However, if the consumer package contains several different types of prophylactic dam, for instance prophylactic dams of different shapes or colours, the identification number is different from the lot numbers.

3.7
individual container
primary package containing a prophylactic dam

3.8
inspection level
relationship between lot size and sample size

NOTE For a description, see ISO 2859-1:1999, 10.1.

3.9
lot
collection of dams of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed with the same lubricant and any other additive or dressing in the same type of individual container

NOTE This International Standard does not specify the size of a lot, but it is possible for a purchaser to do so as part of the purchasing contract. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.

3.10
lot number
number or combination of numerals, symbols or letters used by the manufacturer to identify a lot of individually packaged dams, and from which it is possible to trace that lot through all stages of manufacture up to packaging

3.11
lot test
test to assess the conformity of a lot

NOTE A lot test can be limited to include only those parameters that can change from lot to lot.

3.12
non-visible hole
hole in a dam that is not visible under normal or corrected vision, but is detected by a suitable water leak test

3.13
sampling plan
specific plan that indicates the number of units of product from each lot which are to be inspected (sample size or series of sample sizes) and the associated criteria for determining the acceptability of the lot (acceptance and rejection numbers)

3.14
shelf-life
period of time from the date of manufacture over which the product is claimed to conform to the specified requirements

3.15
visible hole
hole in the dam that is visible under normal or corrected vision before the dam is exposed to water during testing for holes

3.16
visible defect
〈other than hole〉 permanent crease with adhesion of the film, or other materials embedded in the film

4 Quality verification

Dams are produced in large quantities. Inevitably there is some variation between individual prophylactic dams. A small proportion of dams in each production run might not meet the requirements of this International Standard. Furthermore, the majority of the test methods described in this International Standard are destructive. For these reasons, the only practicable method of assessing conformity with this International Standard is by testing a representative sample from a lot or series of lots. Sampling plans referred to in this International Standard are identified in ISO 2859-1. Refer to ISO/TR 8550-1 for guidance on acceptance sampling in general, and to ISO/TR 8550-2 for the selection of alternative acceptance sampling systems, for the inspection of discrete items in a lot. For testing purposes, sampling shall be conducted by lot number, not by identification number. Handling and storage conditions shall be documented before drawing the samples.

Sampling plans shall be selected to provide an acceptable level of consumer protection. Suitable sampling plans are given in Annexes A and B.

Annex A describes sampling plans based on ISO 2859-1 and is most applicable to manufacturers or purchasers assessing the conformity of a continuing series of lots. The full level of consumer protection available depends upon the switch to tightened inspection if deterioration in quality is detected. The switching rules cannot offer full protection for the first two lots tested, but become progressively more effective as the number of lots in a series increases. The sampling plans in Annex A are applicable whenever five or more lots are being tested.

Annex B describes sampling plans, based on ISO 2859-1, which are recommended for the assessment of isolated lots. It is recommended that these sampling plans be used for the assessment of fewer than five lots, for example in cases of dispute, for referee purposes, for type testing, for qualification purposes or for short runs of continuing lots.

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

Where initial or ongoing quality verification for dams is required, it is suggested that, instead of concentrating solely on evaluation of the final product, the party concerned also assess the manufacturer's quality system. ISO 13485 specifies the provision of an integrated quality system.

5 Design

5.1 General

A prophylactic dam is a piece of polymer film that is used to prevent transmission of micro-organisms, which can cause STIs. It is intended to cover the anal area or the external female genitalia. Dams shall be designed to prevent STIs during sexual activity.

5.2 Dressing materials

The dam may be coated with dressing materials intended to protect it in storage, or with flavours or perfumes. Any dressing material used shall be non-cytotoxic, non-sensitizing and non-irritating, respectively, and suitable for human consumption. The dressing material shall not have any deleterious effects on the barrier membrane.

5.3 Dimensions

5.3.1 Length

The length of a dam shall be between 200 mm and 350 mm. When tested in accordance with the method given in Annex C, taking 13 dams from each lot, no measurement shall be outside the specified range.

5.3.2 Width

The width of a dam shall be between 150 mm and 250 mm. When tested in accordance with the method given in Annex C, taking 13 dams from each lot, no measurement shall be outside the specified range.

5.3.3 Thickness

Whenever measured in accordance with Annex D, the mean thickness of the dam shall be not more than 0,15 mm. No single reading shall be below 75 % of the mean and no single reading shall be above 125 % of the mean.

For dams made from natural rubber latex, no single thickness measurement shall be less than 0,04 mm.

5.4 Risk assessment

5.4.1 A risk assessment for the product shall be conducted in accordance with ISO 14971. The assessment shall identify potential failure modes for the device as well as any other safety and efficacy concerns. Manufacturers shall make the results of the risk assessment for the design, as described in Annex E, available to regulatory authorities on request.

5.4.2 The manufacturer shall identify and define all reasonably predictable failure modes during the analysis, and these failure modes shall be considered part of the design of the device.

6 Barrier properties

This clause applies only to products made from materials other than natural rubber latex.

The barrier properties of the dam shall be established by viral penetration studies using a suitable surrogate virus, for example bacteriophage phi-X 174. Where tested in accordance with the method given in Annex F, viral penetration properties shall be compared with those of a hole-free male latex condom that meets the requirements of ISO 4074.

The viral penetration per unit area shall be no more than 150 % of the penetration found for the control dam.

7 Biocompatibility

Biocompatibility for the finished product and its components shall be established in accordance with ISO 10993-1. Since the dam is in repeated contact with surface mucosa and possibly compromised tissue surfaces, the testing shall be conducted to demonstrate that the materials are not cytotoxic and do not cause sensitization, mucosal irritation or acute systemic toxicity, in accordance with the relevant clauses of ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-11, respectively. If there is a likelihood of systemic absorption of any components or residuals, mutagenicity testing shall be performed. All data generated in these evaluations shall be made available to regulatory authorities on request.

The manufacturer shall also obtain, and make available to regulatory authorities on request, toxicity data on all the additives and residual monomers, solvents and known impurities used in the manufacture of the dam subject to this International Standard. Suitable material safety data sheets shall be supplied on request for materials used in the manufacture of products conforming to this International Standard.

NOTE Attention is drawn to provisions in ISO 10993-1 that do not require specific tests on the product, provided it is made from materials whose biocompatibility is already established.

8 Surface finish

Place the barrier membrane (dam) on a light box and examine under normal or corrected vision. The latex barrier membrane should have a smooth surface finish on both sides. It shall be free from ingrained particles, blisters, air bubbles and other imperfections, which would detract from its serviceability.

9 Tensile properties

9.1 Natural rubber latex dams

9.1.1 Tensile strength and elongation

Where tested in accordance with the method specified in Annex G using type 1, type 1A or type 2 dumb-bell test pieces, the minimum tensile strength and elongation at break shall comply with the requirements given in Table 1.

NOTE type 1A dumb-bells are preferable, if available.

9.1.2 Tear resistance

Where tested both longitudinally and transversely in accordance with ISO 34-1, method A (trouser tear test), the minimum value of the tearing force (the force at the onset of tearing) and tear resistance shall comply with the requirements of Table 1.

Table 1 — Minimum tensile properties and tear resistance

Tensile property	Minimum requirements
Tensile strength, MPa	21
Elongation at break, %	650
Tear resistance, N/mm	5
Tearing force, N	0,5

An AQL of 2,5 shall apply.

9.2 Dams made from other materials

9.2.1 General

As part of the risk assessment in 5.4, the manufacturer shall determine suitable minimum values for the tensile strength, elongation at break, tear resistance and tearing force, and make these values publicly available as part of the device specification. Where the material used is already commonly used for other products and its physical properties are published, the minimum values shall be at least similar to the published properties of the material.

9.2.2 Tensile properties

Where tested in accordance with the method specified in Annex G using type 1, type 1A or type 2 dumb-bell test pieces, the minimum tensile strength and elongation at break shall comply with the minimum values developed by the manufacturer. An AQL of 2,5 shall apply to these values.

9.2.3 Tear resistance

Where tested both longitudinally and transversely in accordance with ISO 34-1, method A (trouser tear test), the minimum value of the tearing force (the force at the onset of tearing) and tear resistance shall comply with the requirements developed by the manufacturer. An AQL of 2,5 shall apply to these values.

10 Tests for stability and shelf-life

10.1 General

Manufacturers shall verify that the dams satisfy the requirements for freedom from holes, visible defects, tensile strength and tear resistance given in Clauses 9 and 11 until the end of the labelled shelf-life. Shelf-life claims shall not exceed five years.

Data supporting the shelf-life claims made by the manufacturer shall be made available to the appropriate regulatory authorities and direct purchasers upon request.

Before a new or modified prophylactic dam design is placed on the market, the following requirements shall be met:

a) the dam shall be tested for the minimum stability requirements as described in 10.2;

b) a real-time stability study, as described in 10.3, to determine shelf-life shall have commenced;

c) pending completion of the real-time stability study, shelf-life shall be estimated as described in 10.4.