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BSI Standards Publication

Prophylactic dams — Requirements and test methods

This British Standard is the UK implementation of ISO 29942:2011.

The UK participation in its preparation was entrusted to Technical Committee CH/157, Mechanical contraceptives.

A list of organizations represented on this committee can be obtained on request to its secretary.

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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*