TECHNICAL REPORT

ISO/TR 24484

First edition
2023-01

Female condoms — Use of ISO 25841 and the quality management of female condoms

Préservatifs féminins — Utilisation de l'ISO 25841 et du management de la qualité des préservatifs féminins

Reference number
ISO/TR 24484:2023(E)

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Published in Switzerland

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A female condom is a sheath that completely lines the vaginal canal and is designed to be retained in the vagina during sexual intercourse and after withdrawal of the penis to prevent pregnancy and transmission of sexually transmitted infections (STIs).

Female condoms that meet or exceed the requirements of ISO 25841 are effectively used for contraceptive purposes and in the prevention of sexually transmitted infections (STIs). They have adequate barrier properties, adequate physical properties so as not to break during use, are correctly packaged to protect them during storage throughout the claimed shelf life and are correctly labelled to facilitate their correct use.

ISO 25841 is a quality standard for female condoms, detailing the requirements for establishing the baseline specifications and for testing the finished product for compliance to the predefined specifications. It is applied by manufacturers, procurement agencies, regulatory bodies, and testing laboratories.

ISO 13485 is a generic standard for quality management of medical devices and serves as the requirement for regulatory compliance. The specific quality requirements for female condoms are given in ISO 25841. This document is a document providing manufacturers, buyers, regulatory agencies and third-party test laboratories, information relating to implementation and application of ISO 25841 and ISO 13485 in the quality management for manufacture of female condoms, and for purchasers to develop appropriate purchase technical specifications and to verify that condoms delivered comply with requirements of ISO 25841 and ISO 13485. This document outlines the importance of the requirements of the quality management system based on ISO 13485 that are applied during all the stages of design and development, production, supply, procurement, and post- production related to the complete life cycle of female condoms.

Consistent quality of female condoms, as other medical devices, is achieved by implementation of quality management system as per ISO 13485, which enables that quality is built into the product and assured at every phase in the design, planning, production, procurement processes and post-production activities. The requirements of ISO 13485 include implementation of the requirements ISO 14971 on risk management during all the phases of manufacture.

Female condoms, being medical devices, are subject to regulatory controls by national and regional regulatory agencies. The regulations address both the aspects of product approval and registration and licensing controls on the manufacture and distribution of female condoms. Compliance with the requirements of ISO 13485 and ISO 25841 are essential aspects which form the basis of regulatory approvals.

The specific additional requirements of buyers and consumers are specifically given due consideration when complying with the requirements of ISO 25841, as ISO 25841 is general by design, based on the designs that are currently approved for marketing. There are also specific documented technical specifications such as WHO UNFPA technical Specification on female condoms, which address the requirements of projects and procurement for public distribution programs.

The designs of female condoms, which are currently available in the market or under development, vary considerably with reference to the design of the sheath, the type of retention features, dressing materials, lubricants, etc. Thus, the failure modes of each design of female condom could vary significantly. Therefore, ISO 25841 requires that the efficacy and the safety of each design of female condoms should be substantiated by

a) preclinical evaluations which would include standardization of physical properties, assessment of barrier properties, tests for stability and shelf life and assessment of biocompatibility to ensure the safety of materials that are used in the manufacture of female condoms and their components such as sheath, retention features, dressing materials, lubricants, additives, residual processing aids, etc. as prescribed in ISO 25841, and

b) clinical investigations in humans to establish the efficacy and in vivo safety, as prescribed in ISO 25841, ISO 29943-2, ISO 10993-1, ISO 10993-5 and ISO 10993-10 and if necessary, ISO 10993-3.

Though female condoms are non-sterile medical devices, manufacturers are recommended to implement appropriate measures to minimize microbiological contamination of the product, by exercising controls on the components used in the manufacture of female condoms, manufacturing environment during manufacture of sheath, assembly of condoms and their packaging, manufacturing operations and health and hygiene of personnel.

It is important that properties of female condoms are maintained throughout the shelf life to ensure their safety and efficacy. ISO 25841 requires that the shelf life of any new or significantly modified female condom should be estimated by conducting stability studies as per ISO 25841 and, based on such studies, the appropriate storage conditions should be prescribed. The review of data of the shelf studies is important for granting product approvals and for awarding purchasing requirements.

This document also addresses how to deal with other important issues not directly covered by ISO 25841, but related to effective implementation of quality management system in manufacture of female condoms which will conform to the specifications of ISO 25841.

Female condoms — Use of ISO 25841 and the quality management of female condoms

1 Scope

This document gives the essential principles in the application of ISO 25841. It outlines the details of elements applicable in quality management of female condoms as required by related normative standards, as referred in ISO 25841 and other relevant concepts.

This document supplements the use of ISO 25841 and addresses quality management aspects to be considered during the development, manufacture, quality verification and procurement of female condoms. It encompasses the principles of quality management systems in design, manufacture, and delivery of female condoms with emphasis on their performance, safety and reliability.

This document is applicable to female condoms made of natural rubber or synthetic rubber or synthetic polymers and the retention devices which form the integral components of female condoms.

NOTE Female condoms made from either natural rubber latex or synthetic rubber or other synthetic polymeric materials are addressed in ISO 25841.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes references for 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 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

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

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

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO 25841, *Female condoms — Requirements and test methods*

ISO 29943-2, *Condoms — Guidance on clinical studies — Part 2: Female condoms, clinical function studies based on self-reports*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 2859-1, ISO 9000, ISO 13485, ISO 14971, ISO/IEC 17025, ISO 25841 and ISO 29943-2 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/