



BSI Standards Publication

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

National foreword

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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*



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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 Technical Reports 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.

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).

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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