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Mechanical contraceptives — Reusable natural and silicone rubber contraceptive diaphragms — Requirements and tests

*Contraceptifs mécaniques — Diaphragmes contraceptifs réutilisables
en caoutchouc — Performances et essais*



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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.

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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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

This second edition cancels and replaces the first edition, ISO 8009:2004, of which it constitutes a minor revision. It also incorporates the amendment ISO 8009:2004/Amd1:2012.

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Introduction

Diaphragms are medical devices, therefore, they should be produced under a good quality management system. Reference should be made, for example to the ISO 9000- series, in conjunction with ISO 13485.

The sampling plans and acceptance quality limits (AQLs) given in this International Standard are for referee testing. The AQLs represent the maximum tolerable level of defects in the products. As diaphragms are intended for re-use, manufacturers should strive for entirely defect-free product.

Manufacturers can devise and apply additional and alternative quality control measures for their use and after production. These methods can differ among manufacturers.