

INTERNATIONAL ISO
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First edition
2004-10-01

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

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



Reference number
ISO 8009:2004(E)

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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

Published in Switzerland

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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 8009 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

This first edition cancels and replaces ISO 8009-1:1997, ISO 8009-2:1985, ISO 8009-3:1985, ISO 8009-4:1996, ISO 8009-5:1996, ISO 8009-6:1985, ISO 8009-7:1985, ISO 8009-8:1985, ISO 8009-9:1985 and ISO 8009-10:1985, which have been technically revised and incorporated into one document.

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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 or ISO 13488 as appropriate.

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