
International Standard



8009/9

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Reusable rubber contraceptive diaphragms — Part 9 : Packaging and labelling

Diaphragmes contraceptifs réutilisables en caoutchouc — Partie 9 : Emballage et étiquetage

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8009/9 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

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Reusable rubber contraceptive diaphragms — Part 9 : Packaging and labelling

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1 Scope and field of application

This part of ISO 8009 specifies requirements for the packaging and labelling of reusable rubber contraceptive diaphragms.

2 Packaging

2.1 Individual container

Each diaphragm shall be individually packaged in a container designed to protect it from contamination and mechanical damage during normal handling, transport and storage.

2.2 Outer container(s)

A convenient number of individual containers shall be packed in one or more outer containers which shall be sufficiently robust to protect the contents during transport and storage.

3 Labelling

3.1 Diaphragm identification

Each diaphragm shall be legibly marked with :

- a) the manufacturer's name or recognized mark;

- b) the nominal size, in millimetres.

3.2 Individual container identification

The container, as received by the user, shall be legibly marked with the following information :

- a) the manufacturer's and/or distributor's name or recognized mark;
- b) the manufacturer's lot number;
- c) the nominal size, in millimetres;
- d) the manufacturer's recommended last distribution date (month and year), i.e. the date after which the diaphragm should not be distributed to consumers.

3.3 Instructions

Each individual container shall contain instructions for the use and care of the diaphragm.

NOTE — The annex gives a list of items that should be considered for inclusion in the instructions.

Annex

Examples of information that may be included in the instructions for use

(This annex does not form an integral part of the standard.)

- A.1** With proper care, a diaphragm should remain usable for at least one year.
- A.2** Following child birth, or sudden gain or loss of weight of more than 3 kg, a different size of diaphragm may be advisable.
- A.3** A suitable spermicidal preparation shall be used at all times in conjunction with a diaphragm. Only those spermicidal preparations which have no harmful effect on the material of the diaphragm should be used.
- A.4** After use, wash the diaphragm carefully with soap and water, rinse it and then dry it with a soft clean cloth. The diaphragm should not be heated in order to dry it. Synthetic detergents or organic solvents should **not** be used.

Each time the diaphragm is used and washed, it should be examined carefully to ensure that :

- a) there are no pin-holes or thin spots;
- b) the spring is fully enclosed by the rubber;
- c) the rubber shows no sign of deterioration, for example changes in colour, tackiness.

- A.5** Because of the deleterious effect of oil and petroleum-based greases, including petroleum jelly, these materials should not be used to lubricate diaphragms made of natural rubber. A lubricant based on water-soluble material or other lubricant having no harmful effect on rubber should be used.

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- A.6** Keep exposure to light to a minimum. Store the diaphragm in the container when not in use.