INTERNATIONAL STANDARD

ISO 19351

First edition
2019-07

Fallopian rings — Requirements and test methods

Anneaux de fallope — Exigences et méthodes d'essai

Reference number
ISO 19351:2019(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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).

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 on 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 the following URL: 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

Fallopian rings are devices which provide permanent contraception. These devices are elastic bands made from medical grade silicone. They are implanted bilaterally using a laparoscopic surgical procedure. After the rings are applied to each fallopian tube, they cut off the blood supply and occlude the tubal lumen. This stops the ova from travelling to the uterus, thereby preventing fertilisation. Fallopian rings are provided sterile and packaged as a set of two.

This document has been necessitated as a result of the product marketing experience gained by manufacturers and procurement agencies.

Fallopian rings — Requirements and test methods

1 Scope

This document specifies the minimum requirements and test methods for fallopian rings used for tubal occlusion in women for permanent contraception. This document does not address the applicator or other accessories used to place the fallopian rings.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of 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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-3, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

ASTM F640, *Standard test methods for determining radiopacity for medical use*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
fallopian rings
elastic band made of medical grade silicone placed around a loop of fallopian tube bilaterally using a laparoscopic surgical procedure or open surgery, cutting off the blood supply to occlude the tubal lumen and prevent fertilization

3.2
lot
collection of *fallopian rings* (3.1) manufactured at essentially the same time, using raw materials of the same specifications, the same process and common equipment, packed in the same type of individual container

Note 1 to entry: The recommended maximum individual lot size for production is 10 000 pairs, but it is possible for a purchaser to specify the lot size as part of the purchasing contract and quality management system of the manufacturer.

3.3
lot number
number or combination of numerals, symbols or letters used by the manufacturer to identify a *lot* (3.2) or individually packaged product, and from which it is possible to trace that lot through all stages of manufacture up to packaging

3.4
lot test
test to assess the conformity of a *lot* (3.2)

Note 1 to entry: A lot test may be limited to include only those parameters which may change from lot to lot.

3.5
inspection level
relationship between lot size and sample size

Note 1 to entry: Inspection level designates the relative amount of inspection.

3.6
sampling plan
specific plan which indicates the number of units of products from each *lot* (3.2) which are to be inspected (sample size or series of sample sizes) and the associated criteria for determining the acceptability of the lot (acceptance and of manufacture to the use before date)

3.7
shelf life
period of time from the date of manufacture during which the *fallopian rings* (3.1) are required to confirm to the requirements specified in this document

3.8
radio-opacity
quality or state of being radio-opaque

Note 1 to entry: It is the property of the material in obstructing the passage of radiation energy such as X-rays and will produce a white image on the exposed X-ray film, which confirms that the implanted device is in position.

3.9
visible defects
defects which are visible to unaided eye during inspection, such as discolouration, any fibres or protrusions on the fallopian ring

3.10
laparoscope
instrument inserted through an incision in the abdominal wall and used to visualize the surgical field, where it has working channels with the applicator to insert the *fallopian rings* (3.1)

4 Requirements

4.1 Quality verification

Fallopian rings are mass produced articles manufactured in very large quantities. Inevitably, there will be some variation between individual rings, and a small proportion of rings in each production run might not meet the requirements of this document. Further, the majority of the test methods described in this document are destructive. For these reasons, the only practicable method of assessing conformity with this document is by testing a representative sample from a lot or series of lots. Basic sampling plans are given in ISO 2859-1. Reference should be made to ISO/TR 8550 (all parts) for guidance on the use of acceptance sampling system, scheme or plan for the inspection of discrete items in lots. When on-going verification is required of the quality of fallopian rings, it is suggested that, instead of concentrating solely on evaluation of the final product, attention is also directed at the manufacturer's quality system. It should be noted that ISO 13485 covers the provision of an integrated quality system for the manufacture of medical devices. Sampling plans shall be selected to provide an acceptable level of consumer protection. Suitable sampling plans are given in Annexes A and B.

a) Annex A describes sampling plans based on ISO 2859-1 and is most applicable to manufacturers or purchasers assessing the conformity of a continuing series of lots. The full level of consumer protection available depends upon the switch to tightened inspection if deterioration in quality is detected. The switching rules, described in ISO 2859-1:1999, Clause 9, cannot offer their full protection for the first two lots tested but become progressively more effective as the number of lots in a series increases. Use the sampling plans in Annex A when five or more lots are being tested.

b) Annex B describes sampling plans, based on ISO 2859-1, that are recommended for the assessment of isolated lots. The sampling plans in Annex B provide approximately the same level of consumer protection as those given in Annex A when used with the switching rules. It is recommended that these sampling plans are used for the assessment of fewer than five lots, for example in cases of dispute, for referee purposes, for type testing, for qualification purposes or for short runs of continuing lots.

It is necessary to know the lot size in order to derive the number of fallopian rings to be tested from ISO 2859-1. The lot size will vary between manufacturers and is regarded as part of the process and quality controls used by the manufacturer. If the lot size is not known or cannot be confirmed by the manufacturer, then a lot size of 10,000 fallopian rings shall be assumed for determining the sample sizes for testing.

4.2 Physical requirements

4.2.1 Dimensions

Fallopian rings are tested for the inner diameter and outer diameter in accordance with Annex C and shall conform to the requirements given in Figure 1.

Cut rings shall be free from fibrous protrusions at the outer and inner surface. Angle of cut shall be at 90° (≤5° angulations is allowed).

Dimensions in millimetres

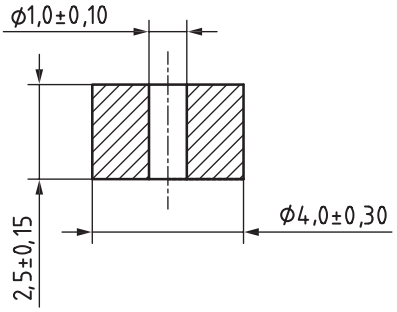


Figure 1 — Fallopian ring

4.2.2 Tensile properties

Fallopian rings tested in accordance with Annex D for the tensile properties shall conform to the requirements stated below.

a) The force at break shall be ≥20,50 N.

b) Elongation at force at break shall be ≥560 %.

4.2.3 Loading force on ring applicator

Fallopian rings tested in accordance with Annex E for the force of loading on ring applicator shall conform to the requirement stated below.

The force required to load fallopian rings on the ring applicator shall be ≤35 N.

4.2.4 Elastic memory

Fallopian rings tested in accordance with Annex F for the elastic memory shall conform to the requirement stated below.

The recovery of the inner diameter shall be such that the increase in the inner diameter ≤25 % of the original diameter.

4.2.5 Repeat loading strength

Fallopian rings tested in accordance with Annex G for the repeat loading strength shall neither break nor develop any cracks when viewed using ×20 magnification.

4.2.6 Visible defects

Fallopian rings tested for the visible defects shall not have defects such as discolouration, any fibres or protrusions on the ring.

4.3 Packaging

4.3.1 Packing mode

One pair of fallopian rings shall be packaged in peel open pouch/blister pack with seal width ≥2 mm.

4.3.2 Primary pouch

Each pouch/blister pack shall ensure:

a) adequate protection of the contents during normal handling, transit and storage for a period of 4 years;

b) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions at a temperature(s) ranging from 0 °C to 50 °C; and

c) minimal risk for contamination of the contents during removal from the pouch/blister pack.

4.3.3 Instruction for use

Every dispenser box shall be provided with at least one instruction for use describing the method to be adopted for:

a) loading of rings on the ring applicator; and

b) storage and handling requirements in clean and dry place.

4.3.4 Package seal strength

Fallopian rings packs shall be tested for package seal integrity and seal strength in accordance with Annex J and peel force shall be 4,4 N to 19,0 N.

4.3.5 Package seal integrity

Fallopian rings packs shall be tested for package seal integrity and seal strength in accordance with Annex J and there shall be no evidence of leakage of the package.

4.3.6 Sterility

Fallopian rings supplied as sterile shall meet the requirements of sterility test as specified in the latest version of national/international pharmacopoeia.

The manufacturer shall establish procedures and systems to validate the type of sterilization used for the fallopian rings as sterility testing alone cannot be deemed as the criteria for confirming the sterility of the product. Validation of ethylene oxide sterilization process shall be done according to ISO 11135 and gamma sterilization shall be done according to ISO 11137-1 and ISO 11137-2.

4.4 Biological requirements

The biological safety of fallopian rings shall be evaluated in accordance with the principles given in ISO 10993-1, according to which fallopian rings are classified as a permanent contact implant device, and the following tests shall be complied with:

a) cytotoxicity as per ISO 10993-5;

b) sensitization as per ISO 10993-10;

c) irritation or intracutaneous reactivity as per ISO 10993-10;

d) subchronic (Subacute) toxicity as per ISO 10993-11;

e) genotoxicity as per ISO 10993-3;

f) acute systemic toxicity as per ISO 10993-11;

g) implantation as per ISO 10993-6.

These tests shall be repeated only in the case of a significant change such as change in formulation or grade of silicone tubing material, change in sterilization method, change in manufacturing process, etc.

The results of the test shall be reviewed and interpreted by a qualified toxicologist.

4.5 Radio-opacity

Fallopian rings shall be radiopaque. This test shall be a type test used for the initial evaluation of the silicone elastomeric tubing material. ASTM F640 shall be referred for determining radio-opacity of the elastomeric material.

4.6 Clinical evaluation

4.6.1 General

Fallopian rings made of silicone-based elastomer have been used to effect female sterilization for nearly 50 years. They have been studied extensively, and clinical reports from the published literature[8] show a long history of safety and effectiveness. Rings manufactured in accordance with the requirements of this document are expected to have comparable clinical performance. This means the manufacturers' fallopian rings are similar to the fallopian rings used in the cited published clinical studies and comply with this document with respect to the following characteristics:

— peak load;

— elongation at peak load;

— strain capacity;

— loading force on ring applicator;

— elastic memory;

— repeat loading strength.

To establish conformance with this document for a new design of fallopian rings, the manufacturer shall demonstrate, using a one-sided test, that the upper limit of the 95 % confidence interval for a one-year pregnancy rate is ≤2,0 %. To establish this, the manufacturer shall sponsor a clinical study of its new design and demonstrate clinical safety and effectiveness. Completion of the one-year phase of the study is sufficient to begin marketing. However, the women in the study should be followed for an additional four years to record any additional pregnancies and serious adverse events.

4.6.2 New clinical study of manufacturer's fallopian rings

A manufacturer may make significant changes to the fallopian ring with respect to design, materials or manufacturing procedures. In this case, the manufacturer shall sponsor a clinical study of its fallopian ring and demonstrate clinical safety and effectiveness. To this end, the sponsor shall conduct a single-arm clinical study, enrolling sexually-active women of reproductive age, following these women for a total of five years. Biostatistical analysis of the study shall show, using a one-sided test, that the upper limit on the 95 % confidence interval for the one-year failure rate (pregnancy) is less than 2,0 %. Completion of the one-year phase of the study is sufficient to begin marketing. However, the women in the study should be followed for an additional four years (a total of five years) to record any additional pregnancies and serious adverse events. Any unusual findings shall be included in updated labelling.

5 Storage condition

The fallopian rings shall be stored at a temperature ranging from 0 °C to 50 °C.

6 Labelling

6.1 If symbols are used on packaging information and marketing materials, the symbols shall meet the requirements as given in ISO 15223-1 and ISO 15223-2.

6.2 Printing and illustrations shall be clear, legible and indelible. If labels are used, they shall be free from gross particulate matter and fibres.

6.3 Each individual container shall be marked with the following:

a) full name and address of manufacturer;

b) batch number;

c) method, month and year of sterilization (for year use four digits);

d) storage directives;

e) use/implant before (specify month and year, or year and month as per the national regulation; use four digits for year).

6.4 In addition to those stated in 6.3, each individual package shall carry the following text:

a) warning-sterile unless package is opened or damaged;

b) fallopian rings shall not be kept loaded on the applicator for more than 15 minutes;

c) a reference to this document (i.e. ISO 19351:2019) and reference to the instructions for use;

d) the pouch/blister pack, once opened, shall not be resealed;

e) any other requirement(s) mandated by the regulatory authorities in the country of use.

7 Shelf life

7.1 General

The fallopian rings shall meet performance specification as per the requirements given in Clause 4 for the complete duration of the declared shelf life.

In case of a significant change in formulation, grade or source of the silicone tubing raw material, change in construction of the primary packing material, sterilization method, or manufacturing process, the shelf life of the fallopian rings shall be established by the following processes.

7.2 Procedure for determining shelf life by real-time stability studies

After testing in accordance with Annex H, the fallopian rings shall meet the requirements given in Clause 4. If the real time data indicate a shorter shelf life than that claimed on the basis of accelerated stability studies, the manufacturer shall notify the relevant regulatory authorities and direct purchasers on the shelf life of the product. The manufacturer shall change the shelf life claim for the product based upon the real time study. In no case shall the shelf life exceed 4 years. Real-time stability studies shall be performed for the full period of the shelf-life claim.

7.3 Procedure for determining shelf life by accelerated stability studies

After testing in accordance with Annex I, the fallopian rings shall meet the requirements given in Clause 4.

Annex A
(normative)

Sampling plan and acceptance criteria for a continuing series of lot

A.1 If a party wishes to establish, by inspection and testing of samples of the final product, whether a continuing series of lots are in compliance with the requirements of this document, the sampling plans and acceptance criteria given in Table A.1 shall be applied.

A.2 Manufacturers may use the schemes in Table A.1 or they may devise and implement validated alternative quality control methods that result in at least equivalent consumer protection.

Table A.1 — Sampling plans and acceptance criteria for a continuing series of lots

Attributes	Inspection level	Acceptance criteria
Dimensions	20 pairs from each lot	All samples shall meet the requirements for dimensions
Tensile properties	Level S3 as in ISO 2859-1	AQL 0,65
Loading force on ring applicator	Level S3 as in ISO 2859-1	AQL 0,65
Elastic memory	Level S3 as in ISO 2859-1	AQL 0,65
Repeat loading strength	Level S2 as in ISO 2859-1	AQL 0,65
Visible defects	20 pairs from each Lot	No discoloration, fibres, protrusions
Package seal integrity and seal strength	Level S3 as in ISO 2859-1	AQL 0,65
Packaging and labelling	20 pairs from each Lot	No printing defects
Sterility	As per National/International pharmacopeia	Shall comply

A.3 Applications for these sampling plans include the following:

a) on-going production testing and quality control by a manufacturer;

b) on-going testing by a purchaser for contractual purposes; and

c) on-going inspection by a regulatory or certification authority.

Annex B
(informative)

Sampling plans intended for assessing compliance of isolated lots

B.1 The sampling plans given in Table B.1, normal inspection, when applied to isolated lots, provide approximately the same level of consumer protection as those given in Annex A when used in conjunction with the switching rules. Attention is drawn to the possibility of using double or multiple sampling plans, which may reduce the total number of fallopian rings that need to be tested to demonstrate compliance when quality is significantly better than the AQLs. Sample sizes may be increased independently of the lot size to achieve a more reliable estimate of lot quantity.

Table B.1 — Sampling plans and acceptance criteria for isolated lots

Attributes	Inspection level	Acceptance criteria
Dimensions	20 pairs from each lot	All samples shall meet the required dimensions
Tensile properties	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Loading force on ring applicator	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Elastic memory	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Repeat loading strength	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Visible defects	20 pairs from each Lot	No discoloration, fibres, protrusions
Package seal integrity and seal strength	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Packaging and labelling	20 pairs from each Lot	No printing defects
Sterility	As per National/International pharmacopeia	Shall comply

B.2 Applications for these sampling plans include the following:

a) type testing as part of a certification procedure;

b) in case where the total number of lots being assessed are insufficient to allow the switching rules to be effective;

c) in case of dispute involving isolated lots, e.g. for referee testing.

Annex C
(normative)

Determination of dimensions

C.1 General

This test is used to determine the dimensions of the fallopian rings.

C.2 Apparatus

C.2.1 Profile projector (minimum × 20 magnification).

C.2.2 Thickness gauge of least count 0,01 mm.

C.3 Procedure

Open the pouch and remove the rings carefully.

Place the ring on the profile projector, and measure the inner diameter and outer diameter.

Thickness of the ring is measured using no load thickness gauge.

The test sampling plan and acceptance criteria are given in Annex A and Annex B.

Test shall be carried at (25 ± 2) °C.

The test report shall be prepared as given in Annex K.

Annex D
(normative)

Determination of tensile properties

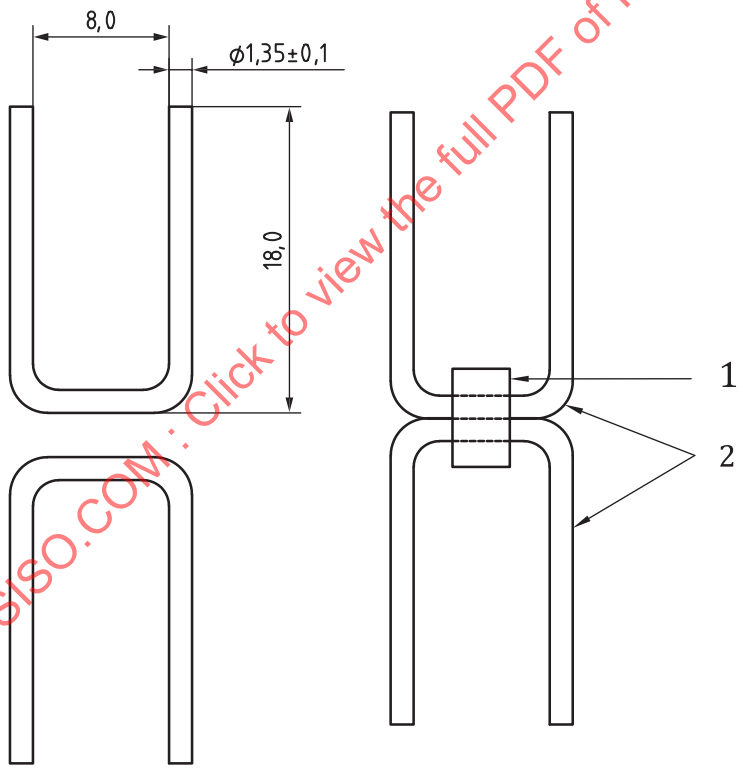
D.1 General

This test is used to determine the force at break (maximum load) and elongation at maximum load.

D.2 Apparatus

D.2.1 U-shaped steel clips.

Dimensions in millimetres



Key

1 fallopian ring

2 U-shaped steel clips

Figure D.1 — Fallopian ring testing using U-shaped steel clips

D.2.2 Universal testing machine (UTM), table top type universal testing machine having the following specification shall be used to perform the tensile test:

— machine type: one–pillar traction;

— drive: motor;

— measuring range: 0 kN to 50 kN;

— test speed: 0 mm/min to 200 mm/min.

D.3 Procedure

D.3.1 The test is performed on a universal testing machine with special adaptors to hold two 'U' shaped steel clips (see Figure D.1). The crosshead separation speed is kept at 100 mm/min.

D.3.2 Place the fallopian rings on two U-shaped steel clips and insert these clips into two adapter tubes, one attached to the fixed crosshead and other to the moving crosshead.

D.3.3 The jaws are separated 100 mm/min and measure the load with the help of a load cell.

Annex E
(normative)

Determination of loading force on ring applicator

E.1 General

This test is used to determine the force required to load the fallopian rings on a ring applicator.

E.2 Apparatus

E.2.1 Example of dilator cone.

Dimensions in millimetres

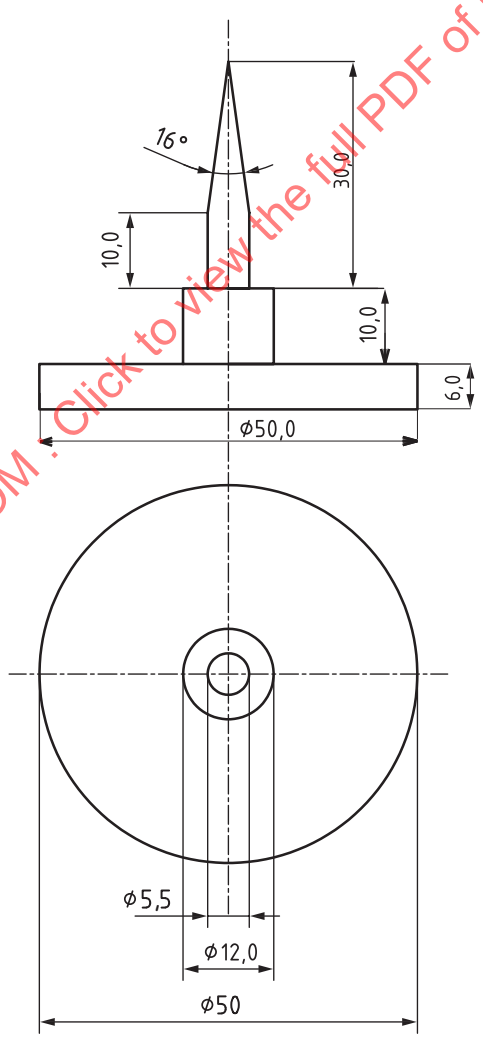


Figure E.1 — Dilator cone

E.2.2 Eye bolt.

Dimensions in millimetres

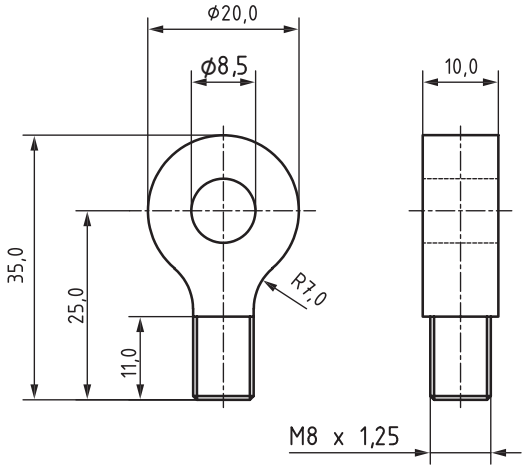


Figure E.2 — Eye bolt (for attaching to UTM)

E.2.3 Adaptor/fallopian rings pusher.

Dimensions in millimetres

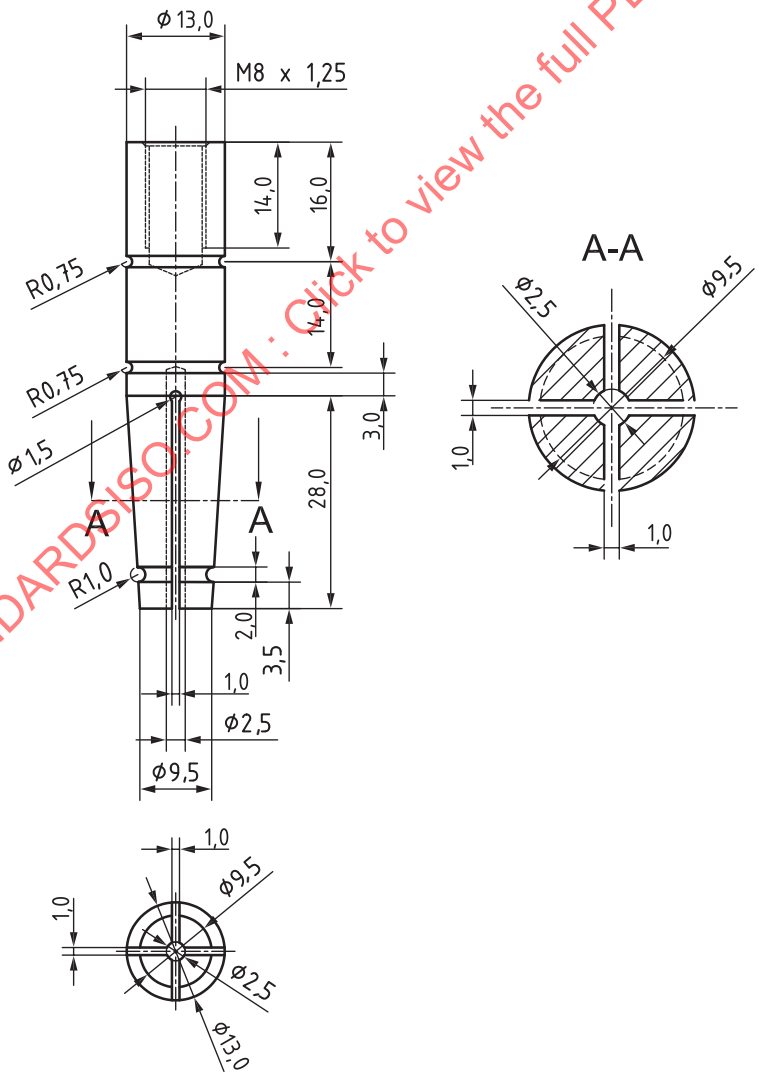


Figure E.3 — Adaptor/fallopian rings pusher

E.2.4 ”O” ring.

Dimensions in millimetres

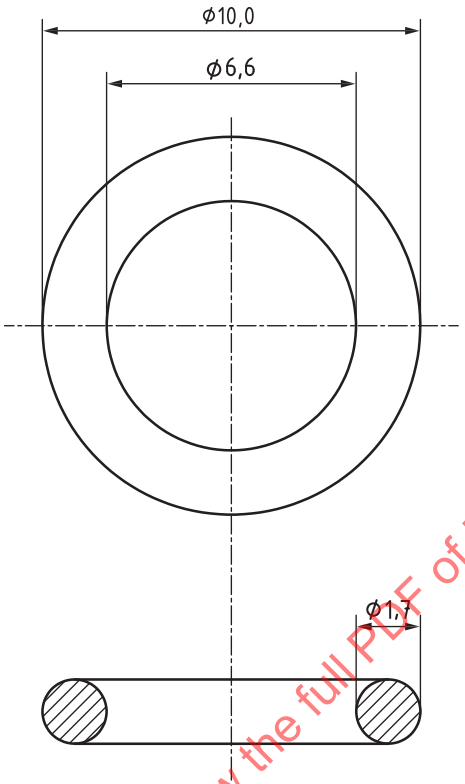
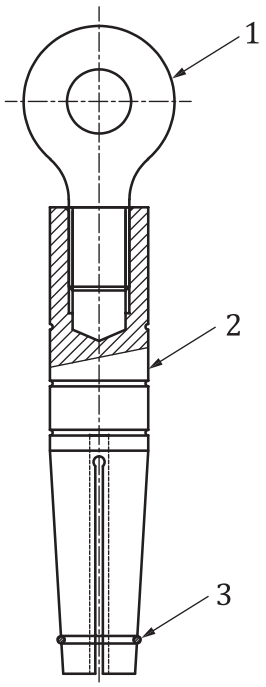


Figure E.4 — "O" ring

E.2.5 Assembly drawing.



1 eye bolt
2 adaptor/fallopian rings pusher
3 "O" ring

Figure E.5 — Assembly drawing

E.3 Universal testing machine (UTM)

Table top type universal testing machine having the following specification shall be used to perform the modulus test:

— machine type: two pillar traction;

— drive: motor;

— measuring range: 0 kN to 50 kN; and

— test speed: 0 mm/min to 200 mm/min.

E.4 Procedure

E.4.1 This test shall be performed on a universal testing machine. A metal disc with a tube-like projection of 5,5 mm outer diameter in the centre which can hold the dilator cone (see Figure E.1) is placed on the compression plate whereas an adaptor (see Figure E.3) which can hold the guide is attached to the moving head using an eye bolt (see Figure E.2). The crossheads of the adaptor are banded together by using a rubber "O" ring (see Figure E.4). The crossheads are brought closer with a speed of 100 mm/min. To test the force, the fallopian rings are loaded on the dilator cone using water as lubricant and the guide is brought right at the top of the dilator cone. The jaw fixed with assembled adaptor (see Figure E.5) is moved closer and the load is measured with the help of a compression cell.

E.4.2 The test sampling plan and acceptance criteria are given in Annex A and Annex B.

E.4.3 Test shall be carried at (25 ± 2) °C.

E.4.4 The test report shall be prepared as given in Annex K.

Annex F
(normative)

Determination of elastic memory

F.1 General

This test determines the capacity of the fallopian rings to recover its inner diameter after stretching to 5,5 mm for an extended period.

F.2 Apparatus

F.2.1 Dilator cone (see Figure E.1).

F.2.2 Profile projector (minimum × 20 magnification).

F.3 Procedure

Measure the initial inner diameter of the fallopian rings using a profile projector.

Load the fallopian rings on a dilator cone for a period of 30 min and then remove and allow recovering its inner diameter under unstretched condition for 1 min.

After recovering for 1 min, measure the inner diameter of the fallopian rings using a profile projector.

The percentage increase in inner diameter is calculated.

The test sampling plan and acceptance criteria are given in Annex A and Annex B.

Test shall be carried out at (25 ± 2) °C.

The test report shall be prepared as given in Annex K.

Annex G
(normative)

Determination of repeat loading strength

G.1 General

This test determines the ability of the fallopian rings to maintain its physical shape and dimensions even after repeated loading and unloading on the band applicator or equivalent fixture.

G.2 Apparatus

G.2.1 Fixture, see Figure G.1.

G.2.2 Profile projector (minimum ×20 magnification).

G.2.3 Programmable stopwatch.

G.3 Procedure

The fallopian rings shall be loaded on a band applicator or equivalent fixture (see Figure G.1) and after keeping it loaded for 20 min, it is unloaded.

The process of loading and unloading is repeated on the same ring for four times after a gap of 1 min between each cycle.

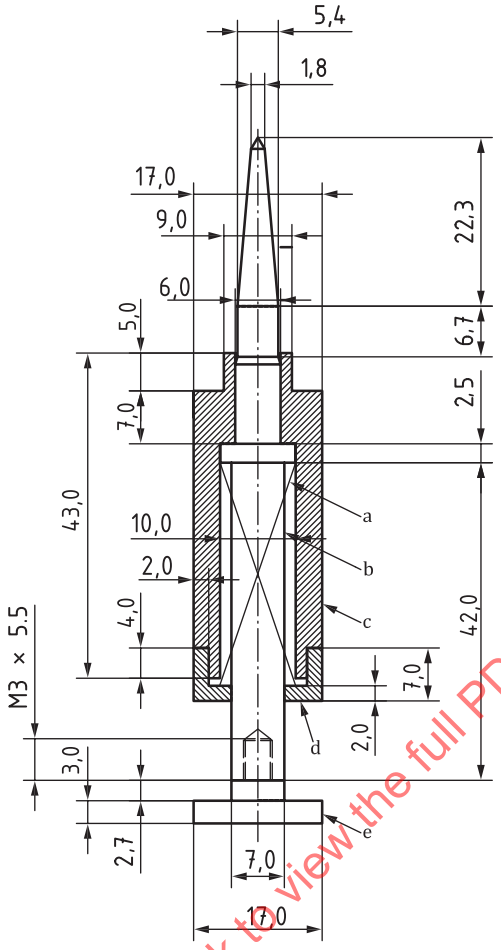
The ring is observed for cracks or breakage. The ring shall neither break nor develop any crack.

The test sampling plan and acceptance criteria are given in Annex A and Annex B.

Test shall be carried at (25 ± 2) °C.

The test report shall be prepared as given in Annex K.

Dimensions in millimetres



a Compression spring.
b Plunger.
c Housing.
d Endcap.
e Stopper.

Figure G.1 — Repeat loading strength test fixture

Annex H
(normative)

Determination of shelf life by real time stability study

H.1 General

Real time stability study shall be conducted under a fixed set of storage conditions to determine use before date of the product.

H.2 Apparatus

Method A: Air-oven method using a cell-type oven or cabinet oven with low air speed and a ventilation of 3 to 10 changes per hour.

Method B: Air-oven method using a cabinet oven with forced air circulation by means of a fan and a ventilation of 3 to 10 changes per hour. The oven equipment and air changes shall be specified and can be of either type but shall be consistent throughout the study.

H.3 Procedure

The study shall be conducted from the representative samples from three consecutive lots manufactured. The rings shall be stored in its primary package under the conditions mentioned in H.4. Sufficient number of samples shall be taken for evaluation of properties mentioned in Table H.1.

Table H.1 — Sampling plans and acceptance criteria

Attributes	Inspection level	Acceptance criteria
Dimensions	20 pairs from each lot	All samples shall meet the required dimensions
Tensile properties	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Modulus	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Elastic memory	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Repeat loading strength	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Visible defects	20 pairs from each Lot	No discoloration, fibres, protrusions
Package seal integrity and seal strength	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Packaging and labelling	20 packages from each Lot	No printing defects
Sterility	As per national/international pharmacopeia	Shall comply
Sterility test shall be performed at-least at the start and end of the real time stability test. It is recommended that additional samples shall be included in the study to allow for re-tests and mistakes.		