International Standard

ISO 14607

Non-active surgical implants — Mammary implants — Specific requirements

Implants chirurgicaux non actifs — Implants mammaires — Exigences particulières

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Foreword

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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 document 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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 14607:2018), which has been technically revised.

The main changes are as follows:

— trace elements subclause (6.4) has been revised;

— language regarding biological evaluation and risk management has been revised and expanded in the general part of the pre-clinical evaluation subclause (7.2.1);

— contamination subclause has been renamed to particulate contamination (7.2.3.8) and completely revised;

— requirements regarding implantation studies have been added (7.2.5);

— clinical evaluation requirements have been expanded (7.3);

— surface category has been added to the label requirements (11.3);

— Annex C “Mechanical tests on a mammary implant in its implantable state” has been expanded and revised;

— the fatigue resistance testing method (Clauses C.1 and C.3) has been revised and expanded;

— Annex F “Test for silicone gel penetration (silicone filling materials only)” has been re-structured and the language has been clarified;

— Annex G “Assessment of silicone diffusion from mammary implants using an in vitro method” has been deleted as the test method given in the annex did not accomplish its purpose;

— Annex H “Test for surface characteristics” has been re-numbered as Annex G and has been renamed “Surface classification”, its status has been changed to normative, it has completely revised and an expanded surface classification has been added;

— Annex J “Tests for surface particulate contamination” has been newly added;

— the language of test report subclauses in all annexes has been harmonized as much as possible.

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

There are three levels of International Standards dealing with non-active surgical implants. These are as follows (with level 1 being the highest):

— level 1: General requirements for non-active surgical implants;

— level 2: Particular requirements for families of non-active surgical implants;

— level 3: Specific requirements for types of non-active surgical implants.

This document is a level 3 standard and contains specific requirements for mammary implants.

The level 1 standard, ISO 14630, contains requirements that apply to all non-active surgical implants. It also indicates that there are additional requirements in the level 2 and level 3 standards.

To address all requirements, the lowest available level is the level to start with.

Non-active surgical implants — Mammary implants — Specific requirements

1 Scope

This document specifies specific requirements for mammary implants. With regard to safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacturing, packaging, sterilization and information supplied by the manufacturer.

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 34-1:2022, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

ISO 37:2024, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 48-4, *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*

ISO/TS 10993-20, *Biological evaluation of medical devices — Part 20: Principles and methods for immunotoxicology testing of medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630:2024, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 21920-2, *Geometrical product specifications (GPS) — Surface texture: Profile — Part 2: Terms, definitions and surface texture parameters*

ASTM D412, *Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension*

ASTM D624-00 (2020), *Standard guide for evaluation of thermoplastic polyurethane solids and solutions for biomedical applications*

ASTM D792, *Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement*

ASTM D2240, *Standard Test Method for Rubber Property — Durometer Hardness*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1, ISO 14155 and ISO 14630 and the following apply.

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

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

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

3.1
anterior projection
maximum height of the implant when placed with its base on a flat horizontal surface

Note 1 to entry: For inflatable and adjustable implants, this applies to the implant's nominal volume.

3.2
base dimension
length of the major axis and the length of the minor axis when the implant is placed with its base on a flat horizontal surface

Note 1 to entry: For inflatable and adjustable implants, this applies to the implant's nominal volume.

3.3
cure
process of cross-linking *silicone polymers* (3.17)

3.4
diffusion
movement of material in and/or out of an implant through an intact *shell* (3.13)

3.5
filling volume
volume of the material contained within the *shell* (3.13) or volume of the solution necessary to fill an inflatable or adjustable *mammary implant* (3.8)

3.6
implant volume
volume of the *shell* (3.13) and filler material together

3.7
injection site
component designed to be penetrated by a needle to alter the volume of the implant

3.8
mammary implant
implant with a *shell* (3.13) which has been filled by the *manufacturer* (3.9) or is designed to be filled by the surgeon, and is intended to add or replace the volume of the breast

3.9
manufacturer
natural or legal person who manufactures or fully refurbishes a medical device, or has a device designed, manufactured, or fully refurbished, and markets that medical device under its name or trademark

[SOURCE: ISO 10993-18:2020, 3.23]

3.10
orientation means
mark in or on the implant to assist the surgeon in positioning the implant

3.11
particle-free water
purified water that has been passed through a suitable filter of 0,22 µm pore size

[SOURCE: USP 43-NF 38 – Reagent Specifications[8]]

3.12
particulate contamination
extraneous particles that are unintentionally present on the surface of an implant

Note 1 to entry: Particulate contamination can come from many sources during the manufacturing process.

3.13
shell
envelope of the *mammary implant* (3.8)

3.14
seam
seal junction of implant materials fused or adhered together

3.15
silicone elastomer
synthetic rubber obtained by the cross-linking of silica-reinforced *silicone polymer* (3.17) chains essentially made of repeated diorganosiloxane units

3.16
silicone gel
semi-solid material consisting of cross-linked *silicone polymer* (3.17) and liquid silicone polymer [silicone oil or polydimethylsiloxane (PDMS)]

3.17
silicone polymer
polymer chains essentially made of repeated organosiloxane units

Note 1 to entry: The silicone polymers can be presented in many levels of viscosity.

3.18
supplier
company which manufactures and/or supplies the raw materials and components used for the production of *mammary implants* (3.8)

3.19
tensile set
tensile elongation remaining after a specimen has been stretched and allowed to relax in a controlled manner

3.20
valve
shell (3.13) component allowing inflation of *mammary implant* (3.8) with variable volumes of liquids when needed and providing a tight closure the rest of the time

4 Intended performance

The requirements of ISO 14630:2024, Clause 4, shall apply.

5 Design attributes

The requirements of ISO 14630:2024, Clause 5, shall apply.

6 Materials

6.1 General

The requirements of ISO 14630:2024, Clause 6, shall apply.

Materials should be manufactured and tested under an appropriate quality management system.

NOTE ISO 13485 is an example of quality management standard, which can be appropriate depending on local or regional regulation.

When materials other than silicone are used, the manufacturer shall establish suitable test methods and acceptance criteria to demonstrate the appropriate performance and safety of the implant.

6.2 Cytotoxicity

Each raw material lot shall be tested for cytoxicity in accordance with ISO 10993-5. The test specimens shall be representative of the materials used in the manufacture of mammary implants and should be cured as appropriate in advance of testing. No cytotoxic effects, as defined in ISO 10993-5, shall occur.

6.3 Silicone gel residual low molecular weight oligomers

The combined residual oligomers, octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6), in uncured or cured silicone gel shall be tested in accordance with Annex A. These shall be reported in mg/kg and the total concentration of D4, D5, D6 combined shall not exceed 150 mg/kg (see also Clause A.9).

6.4 Trace elements

6.4.1 General

The presence of trace elements in raw materials can have two distinct sources.

— The first source is unintentional; they generally are residual substances entrapped into the ingredients used to formulate the raw materials. As such, they can be considered as impurities and shall not be present above a defined content limit, as reported in Table 1.

— The second source is intentional, that is, they are part of the product formulation. Typical examples of such intentional elements are some metals, like platinum (Pt), used under the form of a complex to catalyse the curing reaction of some silicones. In this case, they shall not be considered as impurities and shall rather be taken into account in the larger context of the toxicological evaluation of the implant.

6.4.2 Limits on trace elements present as impurities

Table 1 — Unintentional trace elements impurities limit content

Element	Content limit per element mg/kg
As, Ba, Cd, Co, Cr, Cu, Hg, Mo, Ni, Pb, Pt, Sb, Se, Sn, V	≤10

6.4.3 Intentionally added trace elements

If one of these trace elements is part of the formulation component, it is not considered an impurity.

Two trace elements which are commonly added are platinum (Pt) and tin (Sn).

If the cross-linking reaction of some silicones used for breast implants is catalysed by a platinum complex, the concentration of platinum in the final silicone component after the cross-linking reaction should not exceed 30 mg/kg.

If the cross-linking reaction of some silicones used for breast implants is catalysed by a tin complex, the concentration of tin in the final silicone component after the cross-linking reaction should not exceed 450 mg/kg.

6.5 Physico-mechanical properties and characterization

The following mechanical characteristics of the shell material (e.g. silicone elastomers, after cure) shall be available for every raw material lot:

— elongation at break, in percentage (%), in accordance with ISO 37 or ASTM D412;

— tensile strength at break, in megapascals (MPa), in accordance with to ISO 37 or ASTM D412;

— modulus at 100 % elongation, in megapascals (MPa), in accordance with ISO 37 or ASTM D412;

— hardness, in accordance with ASTM D2240 or ISO 48-4;

— relative density or specific gravity, in accordance with ASTM D792;

— tear strength, in kilonewtons per meter (kN/m), in accordance with ISO 34-1:2022, Method C, or ASTM D624-00 (2020), Die B.

Every raw material lot of silicone gel shall be tested in accordance with Annex F and shall comply with the specifications of the raw material manufacturer.

6.6 Documentation of materials

For each type of material, the manufacturer shall have available a certificate of analysis including at least the following information:

a) supplier's name, address and contact details;

b) material reference;

c) test result including test methods applied for 6.2;

d) for silicone gels test results including sample preparation (e.g. cure condition) for 6.3;

e) test results including the test methods and sample preparation applied for 6.4;

f) test results including defined acceptance criteria, test methods applied and sample preparation (e.g. cure condition) for 6.5.

NOTE This information can typically be obtained from the raw material supplier.

7 Design evaluation

7.1 General

The requirements of ISO 14630:2024, 7.1, shall apply.

An appropriate risk management process in accordance with ISO 14971 shall be established for all stages in the life cycle of the implant.

7.2 Pre-clinical evaluation

7.2.1 General

The pre-clinical evaluation of mammary implants shall conform to ISO 14630:2024, 7.2, and fulfil the requirements of ISO 10993-1.

Under ISO 10993-1, the biological evaluation of any material or medical device intended for use in humans shall form part of a structured biological evaluation programme within a risk management process in accordance with ISO 14971. Part of this risk management process involves the identification of clinical safety signals attributed to the device, biological hazards, the estimation of the associated biological risks and the determination of their acceptability.

The texturing technique, surface roughness, surface complexity and pore size (as described in Annex G), of the breast implant outer surface, shall be taken into account when performing biological evaluation.

The use of extrapolated data from other breast implants can be sufficient to demonstrate biological safety only if these data are from implants with the same surface texturing technique and surface roughness grade as the implant under assessment. See Annex G for details regarding surface texturing technique. More requirements on biological evaluation are described in 7.2.5. When evaluating products with new surface texturing technique all new data shall be generated, unless otherwise justified.

Where no test is described in this document or when the test described is not applicable, the description for the alternative validated test method, the test specimen preparation used and the test results shall be documented by the manufacturer. The adequacy of the pass/fail criteria adopted for the evaluation shall be verified prior to testing.

All testing samples shall be representative of finished sterilized devices.

A worst-case assumption shall be considered.

If the sample size is not specified in the applicable test method, the sample size selected shall be based on a statistical rationale, which shall be justified and documented.

Where appropriate, for materials other than silicone, the manufacturer shall consider and develop tests as indicated in 7.2.2 to 7.2.5.

7.2.2 Mechanical tests

7.2.2.1 Shell integrity

7.2.2.1.1 General

The integrity of the shell shall be evaluated.

The following properties of the silicone elastomer shell shall be tested in accordance with Annex B.

7.2.2.1.2 Elongation

The elongation of the silicone elastomer shell shall be tested in accordance with B.2.1.

7.2.2.1.3 Tensile set

The tensile set of the silicone elastomer shell shall be tested in accordance with B.2.2.

7.2.2.1.4 Strength of joints, seams or seals

The resistance to failure of joints, seams and seals shall be tested in accordance with Clause B.3.

7.2.2.2 Implant resistance

7.2.2.2.1 Fatigue resistance test

The fatigue resistance test shall be conducted in accordance with Clause C.1.

7.2.2.2.2 Impact resistance test

The impact resistance test shall be conducted in accordance with Clause C.2.

7.2.2.2.3 Endurance load level

The endurance load level shall be determined in accordance with Clause C.3.

7.2.3 Physical evaluation

7.2.3.1 Design of shell

The risk of detachment of different layers of the shell from each other and of the shell from the gel shall be evaluated and minimized.

The implant and its outer surface shall be designed to minimize wear debris.

NOTE Wear debris can originate from interaction of the shell with itself or from interaction of the shell with tissue.

The average thickness of any polyurethane or other non-silicone layers used in the shell shall be measured and reported.

The manufacturer shall specify any relevant tests carried out to ensure the suitability of the shell when implanted.

7.2.3.2 Competence of the valve or injection site

If the implant is inflatable, the competence of the valve or injection site shall be tested in accordance with Annex D.

7.2.3.3 Filling material

7.2.3.3.1 General

The physical compatibility between the filling material and the shell shall be demonstrated by providing long-term data on shell performance and integrity.

7.2.3.3.2 Silicone gel cohesion

If silicone gel is used as filling material, cohesivity testing shall be performed in accordance with Annex E.

7.2.3.3.3 Silicone gel penetration

The manufacturer shall specify the acceptance criteria for the silicone gel penetration for the intended use.

Penetration of silicone gel shall be evaluated in accordance with Annex F.

NOTE It is not possible to perform this test on a finished device. Therefore, it is usually performed as a process control (see Clause F.1).

7.2.3.4 Silicone diffusion

Mammary implants shall be designed and manufactured to minimize silicone diffusion.

The manufacturer shall establish appropriate limits for silicone diffusion from the whole finished mammary implant as part of the risk management process.

The manufacturer shall evaluate silicone diffusion from the whole finished mammary implant.

The results of the evaluation shall be considered as part of the risk management process.

7.2.3.5 Volume

The volume of the implants filled by the manufacturer shall be within ±2,5 % of the implant volume stated on the labelling.

7.2.3.6 Dimensions

The actual device base dimensions and anterior projection shall be measured and recorded.

7.2.3.7 Surface texture

If the surface is treated or processed in order to form a specific texture, the texturization method shall be identified, the surface characteristics shall be assessed and the test results shall be recorded.

The surface classification shall be determined in accordance with Annex G.

7.2.3.8 Particulate contamination

Particulate contamination shall be characterized in accordance with the methods described in Clause J.4.

Particulate contamination shall also be characterized with the methods described in Clause J.5 or other methods suitable for soluble particles.

Any results shall be reported in accordance with Clause J.6.

The manufacturer shall conduct a risk assessment on the finished mammary implant to evaluate the risk posed by the particulate contamination, considering the quantity, size, morphology and the chemical identification of the particulate contamination identified in the test. A root cause analysis of particulate contamination on the surface shall be carried out. Where appropriate, measures shall be put into place to reduce or eliminate the source of the contamination and to establish acceptable levels of the identified particulate contamination.

For quality assurance, the manufacturer shall select and justify suitable test methods for periodic testing and shall establish a frequency of periodic testing. It shall be verified that the results of periodic testing are within the pre-specified acceptable levels.

All implant surface contamination tests should be carried out under suitably clean conditions, preferably in a laminar flow cabinet or a clean room.

NOTE The implant surface test according to Annex J is intended to evaluate the cleanliness of the implant surface including the particulates that can be transferred to the device from its own (proper) packaging. It does not evaluate the particulates that can be generated during handling of the packaged device such as during transport, storage and use.

7.2.4 Chemical evaluation

Each shell, filler material and, if applicable, coating material shall be chemically evaluated in accordance with ISO 10993-18.

7.2.5 Biological evaluation

In addition to the general requirements on biological evaluation as included in 7.2.1, the following specific requirements shall be complied with.

— The design and duration of implantation studies shall be conducted as required by ISO 10993-6, implantation studies shall be undertaken for a period exceeding 12 weeks to appropriately reflect the intended duration of the implantation of the device. Implantation studies and immunotoxicology end points, or the immune response (humoral and cellular) to the long-term implantation of the device, shall be evaluated in parallel in accordance with ISO/TS 10993-20. Relevant end points or potential markers attributed to known disease induced by long-term implantation shall be evaluated. Relevant markers for breast implant associated anaplastic large cell lymphoma (BIA-ALCL; e.g. CD 30) should be evaluated when performing implantation and immunotoxicity studies.

— Implantation studies shall be undertaken using one or more appropriate controls that are adequately substantiated as relevant to the device under evaluation. For example, when assessing the implantation effects of a textured implant it is important to include an implant with no texturization as control to meaningfully evaluate the effect of texturing. The implants used in the implantation studies shall be representative of the device under evaluation and device upon which the control is based. These implants can be scaled as appropriate.

7.3 Clinical evaluation

The requirements of ISO 14630:2024, 7.3, shall apply.

As part of the clinical evaluation, estimates shall be made for the frequency and rate at which complications occur, including but not limited to BIA-ALCL, capsular contracture and ruptures or deflation of implants after implantation of a mammary implant.

Where novel findings arise during the clinical evaluation symptoms, complications or disease potentially induced by implants, these findings shall be carefully investigated based on clinical data. In addition, they shall be linked back to the pre-clinical evaluation of the device. Where novel risks arise, new biological safety studies or re-evaluation of the existing data with respect to the novel findings shall be carried out.

Where using extrapolated data from other breast implants to demonstrate clinical safety and performance of an implant, these data shall only be from implants with the same surface texturing technique and surface roughness grade in order to be sufficient. See Annex G for details regarding surface texturing technique.

7.4 Post-market surveillance

The requirements of ISO 14630:2024, 7.4, shall apply.

For implants already placed on the market, clinical data collected through appropriate post-market activities (such as post-market surveillance, post-market clinical studies, registries etc.) can provide supportive evidence for confirming the safety and performance of the implant. The clinical evaluation of this data, in complement with pre-clinical evaluation, can help to understand the suitability of clinically relevant aspects of the implant's safety and performance, including, for example, the suitability of the shell.

8 Manufacturing

8.1 General

The requirements of ISO 14630:2024, Clause 8, shall apply.

Mammary implants and its components shall be manufactured in a validated clean and controlled environment. The level of cleanliness required for each manufacturing step shall be established based on a risk assessment.

9 Sterilization

The requirements of ISO 14630:2024, 9.1, 9.2 and 9.4, shall apply.

Implants shall be supplied sterile.

10 Packaging

The requirements of ISO 14630:2024, Clause 10, shall apply.

Packaging design shall be validated in accordance with ISO 11607-1.

11 Information supplied by the manufacturer

11.1 General

The requirements of ISO 14630:2024, 11.1 and ISO 20417:2021 shall apply.

The information shall be supplied by the manufacturer on the label, package insert or any other media (e.g. user manual, patient information).

NOTE Information supplied by the manufacturer can be subject to national or regional regulations.

11.2 Marking on implants

In addition to the requirements of ISO 14630:2024, 11.2, the implant volume shall be indicated on the implant.

11.3 Label

The requirements of ISO 14630:2024, 11.3, shall apply.

Additionally, the label shall include at least the following details necessary for identification of the implant:

a) implant dimensions (base dimensions, anterior projection and implant volume);

b) filling volume, for inflatable or adjustable mammary implant; and

c) surface classification (texturization method, average roughness and surface complexity, and pore size) in accordance with Table G.2.

11.4 Instructions for use

The requirements of ISO 14630:2024, 11.4, shall apply.

In addition, the manufacturer shall ensure the information specified in Annex H is contained within the instructions for use.

11.5 Patient record label(s)

The package shall include label(s) for use on the patient record and implant card, including at least the following information:

a) the manufacturer identification;

b) the manufacturer's serial number or lot code;

c) the commercial reference of the implant;

d) the implant volume;

e) the unique device identification (UDI) in an automatic identification and data capture (AIDC) format and UDI-DI in a human readable interpretation (HRI).

11.6 Additional information for the user

The manufacturer shall provide the user with the information specified in Annex H.

In addition, at least the following information shall be provided for the user in a manner that is easily accessible, for example, provided on a webpage or requested:

a) a document summarizing the clinical safety and performance of the device;

b) the information specified in 11.8, including instructions on how to access the webpage specified in 11.8.1;

c) a link to a dedicated easily accessible webpage shall be provided for each device that allows providers involved in the care of breast implant patients to regularly monitor changes to the patient brochure and instructions for use; the information on the webpage shall be reviewed and updated regularly as additional data are collected with post-market experience.

11.7 Information on expected lifetime

The manufacturer shall provide information on the expected duration of performance of the device as intended, preferably expressed as percentage implant durability at 10 years (or earlier if 10-year information is not yet available), in accordance with the Kaplan Meier method or an alternative statistical method. Such relevant information includes the indication of factors that can have a significant influence on the actual lifetime of an individual implant.

The source of the expected lifetime information should be provided, for example, from analysis of clinical data generated in a study, from post market data or through in vitro testing simulations under clinically relevant conditions.

NOTE In practice, it is not possible to predict accurately the actual lifetime of an individual implant. It is well understood that several factors are beyond the control of the manufacturer. These factors can have a significant effect on the lifetime of an individual device. The factors include the actual implantation procedure, the anatomy and state of health of the patient, the behaviour and activities (e.g. sporting activities), as well as predictable and unpredictable external mechanical influences.

EXAMPLE Possible methods to provide information on the expected duration of performance of the device as intended include indicating:

a) a probability of lifetime reaching an expected value;

b) a range of the anticipated lifetime;

c) statistical information derived from data obtained by means of similar devices already implanted.

11.8 Information for the patient

11.8.1 General

Two types of information shall be prepared by the manufacturer of the mammary implant in a language accessible or understandable by the patient:

a) patient information in the form of a patient information brochure specific to the breast implant, in accordance with 11.8.2 and as defined in Annex I; this shall be prepared as a standalone document separate to the instructions for use, in a language suitable for the lay person;

b) implant card to be given to the patient after the procedure in accordance with 11.8.3.

This information shall additionally be available via a weblink where the patient can access the most current information intended for the patient for the specific implant model the patient received, including updates to information.

11.8.2 Patient information brochure

The manufacturer shall provide the user with the patient information brochure destined for the patient, as specified in Annex I.

The brochure shall be prepared by the manufacturer in a printed format intended to be given to the patient by the user during the consultation or consenting process ahead of the surgery, to ensure adequate time for the patient to consider their decision to proceed with the surgery.

This information shall not be provided within the sterile barrier of the implantable device packaging.

NOTE The manufacturer is not responsible for the transfer of information from the user to the patient, nor for having the patient sign the consent form.

11.8.3 Implant card

The package shall include an implant card for the user to complete and give to the patient. The requirements of ISO 14630:2024, 11.6 shall apply.

NOTE The manufacturer is not responsible for handing over the implant card to the patient.

The manufacturer shall provide an implant card for delivery to the patient immediately following the implantation procedure. The implant card shall be clearly designed so that the physician can easily identify it and provide it to the patient immediately following the implantation procedure. The information shall be written in a way that is readily understood by a lay person.

The implant card shall contain at least the following, either on the implant card itself or on the patient record label to be added to the implant card:

a) a description of the implant including the surface classification in accordance with Annex G;

b) the UDI;

c) the weblink address of the manufacturer as described in 11.8.1, where the patient can access the most current information for the patient for the specific implant model.

Blank fields for the following patient identification information shall be available on the implant card:

— the patient name or ID;

— the implantation date;

— the name and address of the healthcare institution where the implantation was performed.

Annex A
(normative)

Determination of D4, D5 and D6 in silicone gels

A.1 Objective

This annex describes a quantitative technique for the determination of octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5), and dodecamethylcyclohexasiloxane (D6) in silicone gel or its uncured state. The method described in this annex is intended for the qualification of raw materials.

A.2 Principle

The quantitative analysis of D4, D5 and D6 in silicone gel or its uncured state is carried out using a gas chromatograph (GC) equipped with a flame ionizing detector (FID) and a capillary column or using a gas chromatograph with a mass spectrometer (GC-MS). When using a gas chromatograph without a mass spectrometer, the identification of D4, D5 and D6 in the silicone gel or its uncured state is determined by comparing the retention times of the eluted molecules found in the silicone gel or its uncured state to the known retention times of D4, D5 and D6 as determined through the analysis of D4, D5 and D6 calibration standards. When using a gas chromatograph with a mass spectrometer, the identification of D4, D5 and D6 in the silicone gel or its uncured state is determined by comparing the mass spectra of the test specimen to a mass spectra reference library. The concentration of D4, D5 and D6 in the silicone gel or its uncured state is determined using calibration curves developed through the analysis of D4, D5 and D6 calibration standards at known concentrations. Calibrations may be performed using either an internal or an external calibration standard. The results shall be reported to the nearest milligram per kilogram (mg/kg).

A.3 Test specimen preparation

The silicone gel or its uncured state can be analysed. The raw materials for the silicone gel shall be mixed in accordance with the material manufacturer's recommended mixing procedure.

If the silicone gel is analysed in its cured state, the silicone gel shall be cured in accordance with the material manufacturer's recommended cure schedule. The cured gel shall be extracted with a non-polar solvent, such as n-hexane or dichloromethane, and only the supernatant shall be injected.

If the uncured state is analysed, the uncured materials shall be diluted using a volatile organic solvent and only the supernatant shall be injected.

A.4 Reagents

A.4.1 Non-polar solvent.

A.4.2 Volatile organic solvent (GC grade), as required.

A.4.3 D4, D5 and D6 calibration standards (≥99 % purity).

A.4.4 Internal or external standard (≥99 % purity).

A.5 Apparatus

A.5.1 Gas chromatograph with FID or GC-MS.

A.5.2 Analytical balance.

A.5.3 Gas chromatograph syringe.

A.5.4 Transfer pipettes.

A.5.5 Glass vials.

A.6 Experimental precautions

The usual safety recommendations apply and the following precautions shall be taken.

a) The same gas chromatography parameters shall be used for the analysis of the test specimen as those used for the analysis of the calibration standards.

b) The results shall not be extrapolated beyond the established calibration range.

c) Rinse glassware and flush gas chromatograph syringe with the same volatile organic solvent as used for the test specimen analysis.

d) Prior to the test specimen analysis, verify that the calibration is valid for the range used for measurement.

e) The volatile organic solvent shall be chemically non-reactive with the internal/external standard, the calibration standards and the test specimen.

f) The internal standard, the calibration standards and the test specimen shall be soluble in the volatile organic solvent.

g) The solvent peak(s), when analysed via gas chromatography, shall not interfere with the internal standard peak or the calibration standards peaks.

A.7 Procedure

A.7.1 Number of experiments

The experiment shall be carried out on three test specimens; i.e. three test specimens shall be prepared and analysed via gas chromatography.

A.7.2 Preparation of calibration standards and construction of calibration curves

Prepare a series of D4, D5 and D6 calibration standards at various concentrations such that the calibration range will bracket the expected D4, D5 and D6 concentrations of the test specimen. The calibration range shall be adjusted if the D4, D5 or D6 concentration measured in the test specimen exceeds the established calibration range.

Turn on the gas chromatograph in accordance with the gas chromatograph manufacturer's recommended procedure. Verify that the gas chromatograph is functioning properly and is capable of performing the analysis.

Analyse the calibration standards using the same gas chromatography parameters as will be used for the analysis of the test specimen. Construct a calibration curve (response factor versus known analytic concentration) for D4, D5 and D6 and verify the calibration by determining the linearity of the calibration curves via linear regression (see Clause A.10).

A.7.3 Test specimen analysis

Turn on the gas chromatograph in accordance with the gas chromatograph manufacturer's recommended procedure. Verify that the gas chromatograph is functioning properly and is capable of performing the analysis. The gas chromatography method shall be validated by determining the selectivity, accuracy, range, robustness, precision and limit of quantitation (see Clause A.10). A calibration verification and a method blank shall be performed prior to the test specimen analysis.

Analyse the test specimen using a validated gas chromatography method (see Clause A.10). The same gas chromatography parameters shall be used for the test specimen analysis as were used for the calibration standards analysis. Determine the concentration of D4, D5 and D6 in the test specimen and verify that the concentrations of D4, D5 and D6 fall within the established calibration range. Results are not valid if the results exceed the established calibration range.

A.8 Calculation

Calculate the concentrations of D4, D5 and D6 for the analysis as a mass fraction to the nearest milligram per kilogram (mg/kg).

Record

a) the results from the analysis, and

b) the limit of quantitation (LOQ).

A.9 Specification

The total concentration of D4, D5, D6 combined shall not exceed 150 mg/kg for any of the three test specimens.

A.10 Analytical validation

The test method shall be validated in accordance with the following and summarized in a validation report. Justification shall be provided in the validation report if any of the following items do not apply.

a) Specificity shall be established by verifying the ability to assess the analytes of interest (D4, D5 and D6) in the presence of other components which can be expected to be present.

b) Linearity shall be established across the range of use utilizing a minimum of five different concentrations of a calibration standard.

c) The correlation coefficient for each calibration curve shall be a minimum of 0,98.

d) The accuracy shall be established across the range of use with a minimum of three concentration levels. The percent recovery shall be 80 % to 120 %.

e) Precision shall be established across the range of use.

f) Robustness shall be determined by examining the reliability of the analysis with respect to deliberate variations in method parameters (e.g. different gas chromatograph columns, carrier gas flow rates).

g) The LOQ shall be determined by using acceptable analytical technique, such as measuring the signal-to-noise ratio or determining the standard deviation of the response and the slope, and the LOQ shall be verified.

NOTE Further information on analytical method validation can be found in ICH Guideline Q2(R2).[11]

A.11 Test report

In the test report, at least the following information shall be recorded:

a) a description of the test specimen, including the manufacturer's name and the lot number;

b) a reference to this document and to the method in Annex A, i.e. ISO 14607:2024, Annex A;

c) the date of the test;

d) the identity of the responsible tester;

e) the test method used, including any deviations from the procedure;

f) the test equipment used;

g) the test results;

h) any unusual features observed.

Annex B
(normative)

Tests of shell integrity

B.1 Test specimen preparation

Unless otherwise indicated in this clause, all test specimens shall be prepared using die Type 2 in ISO 37:2024. Where the implant is prefilled, the silicone gel or other material shall be removed. The tests shall include mandrel marks or orientation means if these are present on the shell. If required, isopropyl alcohol should be used to aid test specimen cleaning.

The tests are most conveniently carried out using a commercially available tensile testing frame. In all cases, the test specimen shall be securely clamped at either end and then extended at a constant rate of (500 ± 10) mm/min.

B.2 Shell material

B.2.1 Elongation

Elongation shall be determined in accordance with the requirements of ISO 37.

Elongation shall be a minimum of 450 %.

B.2.2 Tensile set

The test shall be carried out in accordance with the requirements of ISO 37.

The test specimen shall be elongated to (300 ± 15) %, maintained at this elongation for (3,0 ± 0,3) min and then relaxed to the starting position. After this, within 1 min, the tensile set shall be a maximum of 10 %.

B.3 Strength of seams

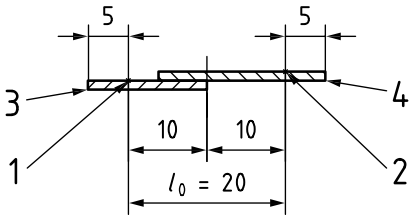
B.3.1 General

The test specimen shall be prepared as outlined in Clause B.1.

The test specimen shall be taken such that the seam region is within the reference portion of the test specimen.

The testing configuration shall be as illustrated in Figure B.1.

Dimensions in millimetres



Key

1 reference mark for the extensometer on the patch
2 reference mark for the extensometer on the shell
3 area of fixation for the grip on the test specimen patch
4 area of fixation for the grip on the test specimen shell
l_0 reference portion of the test specimen

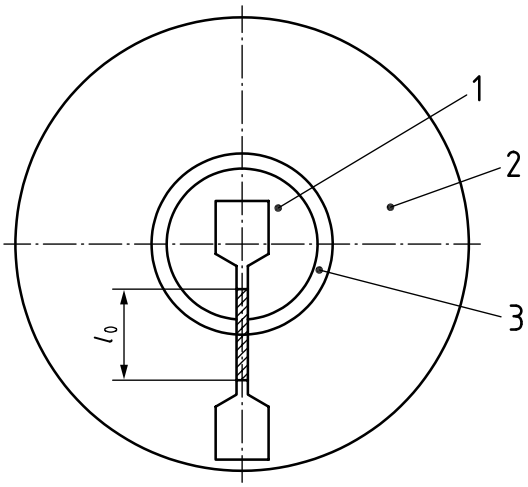
Figure B.1 — Specimen loading configuration

Due to the wide range of the bonded area, it is not always possible for l_0 to equal to 20 mm. In this case, a value of l_0 greater than the width of the bonded area shall be determined by the manufacturer. The bonded area shall be placed in the middle of the l_0 distance and the tensile area.

B.3.2 Critical seams

The test specimen shall be taken as indicated in Figure B.2.

The area of the test specimen designated l_0 in Figure B.1 and Figure B.2 shall not fail when elongated to (300 ± 15) % and maintained at this value for a period of (10 ± 1) s.



Key

1 patch
2 shell
3 junction
l_0 reference portion of the test specimen

Figure B.2 — Test specimen

B.3.3 Non-critical seams

The area of the test specimen designated l_0 in Figure B.1 and Figure B.2 shall not fail when elongated to (100 ± 5) % and maintained at this value for a period of (10 ± 1) s.

NOTE Non-critical seams to shell integrity include fixations, suture tabs, orientation marks and valve covers.

B.4 Test report

In the test report, at least the following information shall be registered for each shell integrity test:

a) the sample size (number of test specimens assessed);

b) a description of implants from which the test specimens are taken, including the manufacturer, the model and the serial number;

c) a reference to this document and to the method in Annex B, i.e. ISO 14607:2024, Annex B;

d) the date of the test;

e) the identity of the responsible tester;

f) the test method used, including any deviations from the procedure;

g) the test equipment used;

h) the test results, in accordance with to B.2.1, B.2.2 and B.3.2 and, if applicable, B.3.3;

i) any unusual features observed.

Annex C
(normative)

Mechanical tests on a mammary implant in its implantable state

C.1 Fatigue test

C.1.1 Principle

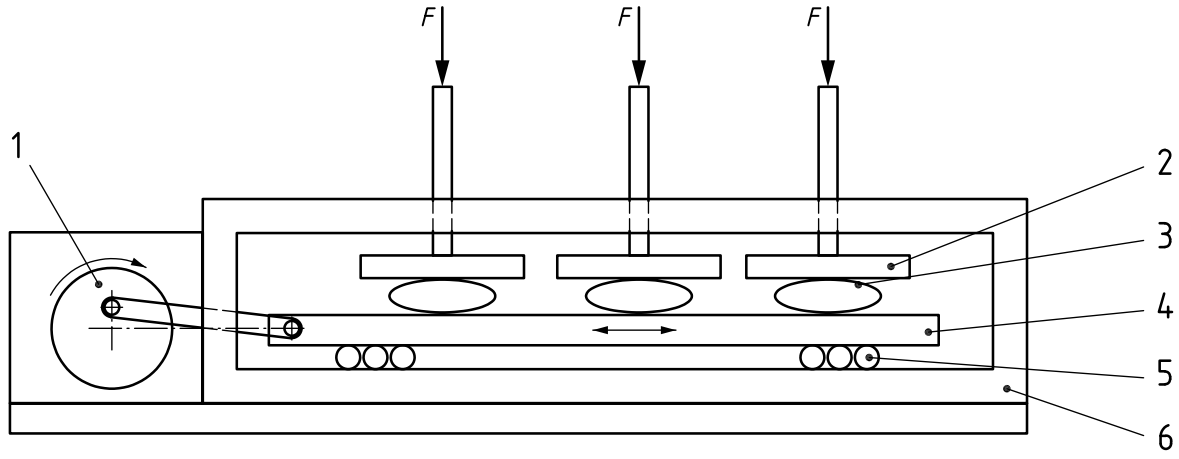
This test method determines the resistance of the implant to fatigue.

C.1.2 Materials

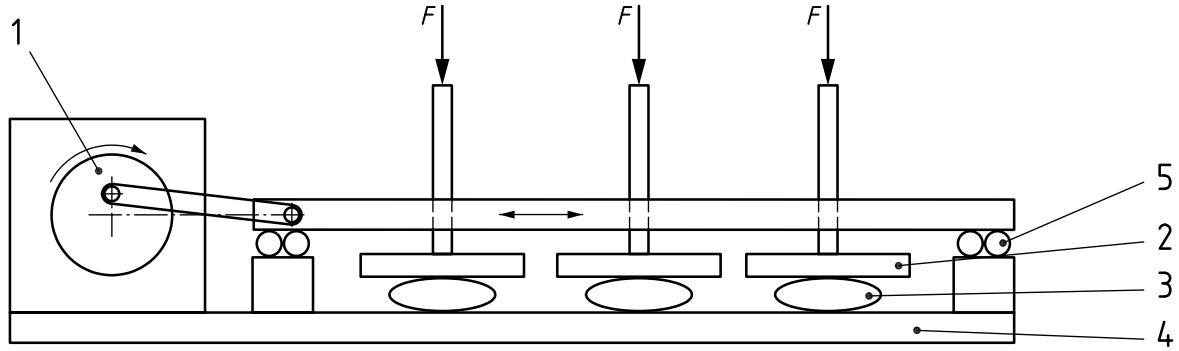
Mammary implant to be tested. Inflatable implants shall be filled in accordance with the manufacturer's instructions prior to the test.

C.1.3 Apparatus

A schema of the apparatus is shown in Figure C.1. It consists of two plates, one being attached to a motor via a connecting arm, which generates alternating shear motion between the plates. The apparatus also includes a mechanism for applying a static compressive load by one of the plates.



a) Apparatus with an upper plate as a loading plate and with a bottom plate as a shearing plate



b) Apparatus with an upper plate as a shearing plate and loading plate

Key

1	motor for alternating motion of shearing plate	5	linear ball bearing
2	upper plate	6	load frame
3	implant specimen	*F*	static compression load
4	bottom plate		

Figure C.1 — Shear fatigue test apparatus

The plate surfaces should be made from appropriate material to prevent slipping between the mammary implant and the plate, e.g. acrylic glass, polymethylmethacrylate or similar. If another material is used, its ability to prevent slipping shall be verified.

The compression load may be applied by one of the following means:

— adding weight to the upper plate, or

— using a load-controlled actuator.

The apparatus shall be capable of applying an average static load of (50 ± 5) N during the entire test.

The apparatus shall be capable of applying a cyclic shear motion sufficient to satisfy the requirements in C.1.4.

Static load and shear motion should be verified periodically, e.g. annually.

C.1.4 Procedure

Before compressing the implant, the shearing plate shall be in its neutral position (0 mm of shear).

The highest point of the implant's profile shall be aligned with the compression load axis, i.e. the centre of the loading plate (see Figure C.2).

a) Round implant **b) Anatomical implant**

Key

1	upper plate in neutral position	3	bottom plate in neutral position
2	round implant aligned centrally with the load axis	4	anatomical implant: highest point of the implant's profile aligned centrally with the load axis
F	static compression load		

Figure C.2 — Alignment of the mammary implant between the plates: Round shape and anatomical shape

Record the position of the implant on the plates in order to compare the implant's position before and after the test.

It should be confirmed that there are no wrinkles or folds at the implant's surface in contact with the plates.

The total length of travel of the shearing plate shall be dependent on the implant's projection height under compression. Measure the projection height p under (50 ± 5) N compressive load and set the total length of travel to 0,75 × p, which is 0,375 × p in each direction.

The allowed tolerance for total length of travel is 10 %. The motor shall be controlled to produce (200 ± 20) cycles per minute, which corresponds to a frequency of (3,33 ± 0,33) Hz.

Anatomically shaped implants shall be aligned in cranial-caudal direction with the movement direction of the shearing plate to simulate the effect of the up and down movement of the body.

The test shall be performed on at least three equivalent samples at an ambient temperature of (23 ± 2) °C, as follows.

a) Move the shearing plate to its neutral position.

b) Place the implant between the two plates and apply the compression load as described in C.1.3.

c) Measure the projection height, p, under compression load.

d) Adjust the drive for alternating motion such that the total length of travel is applied depending on p.

e) Start the shear mechanism to generate the alternating motion of the shear plate.

f) The test shall proceed for a minimum of $6{,}5 \times 10^6$ cycles or until the sample fails.

g) Inspect the implant in accordance with C.1.5.

C.1.5 Requirements

Following this test, no rupture of the implant shell shall be present on the mammary implant when observed visually.

Marks from the testing friction of the support plates shall not be considered as implant failures.

C.1.6 Test report

The test report shall include at least the following:

a) the sample size (number of mammary implants assessed);

b) a description of specimens, including the manufacturer's name, the model, the serial numbers or batch numbers, and the measured compressed projection height, p, of the implant;

c) a description of the test equipment, the total length of travel and the compression load used;

d) the number of run-out cycles;

e) a reference to this document and to the method in Clause C.1, i.e. ISO 14607:2024, Clause C.1;

f) the test results; in case of failure, a description of the failure visually observed and the number of cycles reached;

g) the photographs of the samples after the test; in case of failure, a photograph of the sample should be taken before removing it from the test setup, if practicable;

h) the test start date and the test end date;

i) the identity of the responsible tester;

j) any deviations from the procedure;

k) any unusual features observed.

C.2 Impact resistance test

C.2.1 Principle

This test method determines the impact resistance of mammary implants. The test is based on the vertical drop of a specified mass on the implant. The implant is subjected to an impact force proportional to the mass of the implant. The implant force is varied by adjusting the vertical distance from which the mass of (4,4 ± 0,1) kg may fall.

The drop height is given by Formula (C.1):

$$H = 0,95\, M_{\text{implant}} \frac{1}{1} + 144 \qquad \text{(C.1)}$$

where

H is the drop height, in mm;

M_{implant} is the implant mass, in g.

C.2.2 Apparatus

The apparatus is shown schematically in Figure C.3. It consists of a frame equipped with a mobile gantry to which a total mass of (4,4 ± 0,1) kg is attached. When disconnected from the gantry, the mass runs freely on two guide runners, which ensures a regular and reproducible drop to the base of the frame. A metal plate of (250 ± 5) mm diameter comes into contact with the implant.

The gantry contains a fixing mechanism such that it can be positioned on the frame at a variable height from the base. The frame may include a height gauge and manual winch for positioning, and the gantry may include an electronically controlled release mechanism for the mass.

When the mass holding mechanism is released, the mass falls on the implant. The force generated is proportional to the starting height.

C.2.3 Procedure

Inflatable implants shall be filled in accordance with the manufacturer's instructions prior to the test.

The test shall be performed on at least three equivalent samples as follows.

a) Weigh the implant.

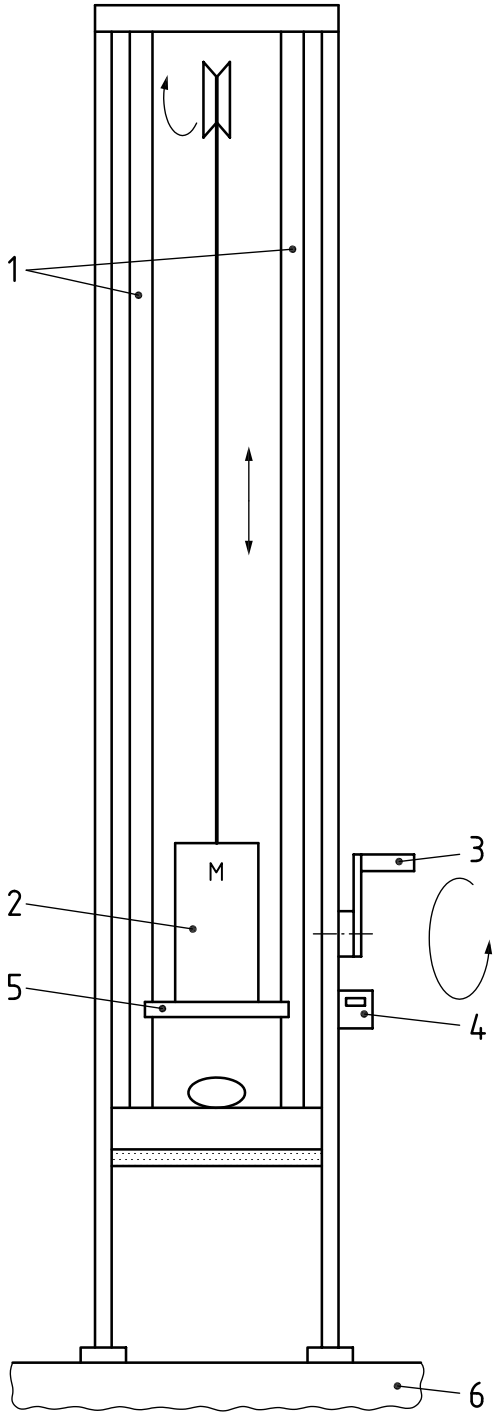
b) Calculate the drop height (in millimetres) in accordance with the implant mass and Formula (C.1).

c) Note the anterior projection and position the gantry, such that the total distance between the impact weight and the frame base consists of the calculated drop height and anterior projection.

d) Position the implant on the frame base, centred directly beneath the impact plate.

e) Release the mass retaining mechanism.

f) Inspect the implant.



Key

1	guide runners	4	height gauge
2	mobile gantry	5	impact plate
3	manual winch	6	frame base

Figure C.3 — Impact resistance test apparatus

C.2.4 Requirement

No rupture of the implant shell shall be present on the mammary implant after the impact resistance test, when observed visually.

All of the tested mammary implants shall fulfil this acceptance criteria.

C.2.5 Test report

In the test report, at least the following information shall be reported:

a) the sample size (number of mammary implants assessed);

b) a description of the specimens, including the manufacturer, the model, the serial number and the anterior projection;

c) a description of the test equipment used;

d) a reference to this document and to the method in Clause C.2, i.e. ISO 14607:2024, Clause C.2;

e) the date of the test;

f) the identity of the responsible tester;

g) the test results; in case of failure, a description of the failure visually observed;

h) any deviations from the procedure;

i) any unusual features observed.

C.3 Endurance load level

C.3.1 Principle

This test method determines the fatigue strength of the final, sterilized device based on the generation of an applied force versus number of cycles to failure (AF/N) diagram.

C.3.2 Materials

Mammary implant [worst case, final, sterilized device(s) with the thinnest shells allowed by the design release criteria].

Inflatable implants shall be filled to the maximum level in accordance with the manufacturer's instructions prior to the test.

C.3.3 Apparatus

C.3.3.1 Use a testing machine which has the following characteristics:

a) the ability to apply a cyclic load in accordance with C.3.4 at the chosen frequency or the ability to apply a cyclic displacement in accordance with C.3.4 at the chosen frequency;

b) a tolerance in applied load or displacement that is not greater than ±2 % at largest load or largest displacement applied;

c) a dynamic loading or displacement waveform that is sinusoidal at the primary frequency;

d) an instrumentation to monitor the values of the maximum and minimum loads and the vertical displacement of the actuator with an uncertainty lower than ±1,0 mm to stop the machine if compression exceeds a prescribed value.

C.3.3.2 Use compression plates which have the following characteristics:

a) a flat metal plate attached to the actuator of the testing machine (mobile plate);

b) a flat metal plate attached to the load frame or load cell of the testing machine beneath the mobile plate;

c) both plates in horizontal orientation, parallel to each other, capable of compressing the mammary implant between them, large enough so that the implant will not extend over the outer diameter of the plates under largest compression.

An exemplary test setup for the endurance load level test is given in Figure C.4.

C.3.4 Procedure

The aim of the test is to generate an AF/N diagram for each style of device tested. Therefore, the samples are cyclically loaded at varying load levels or displacements. A minimum of three samples shall be tested at a given load or displacement level because of the general variance seen in elastomer testing. The endurance load level (or the load at which the samples do not fail under cyclic loading) is established at $6{,}5 \times 10^6$ cycles runout.

In order to generate the AF/N diagram, start with a high load level, e.g. 1 000 N. The load level is defined as the peak load of a sine wave, whereby the valley load should be 50 % of the peak load (R = 0,5). Depending on the result of the first load level (at least one rupture or only runouts), the second load level is set lower in case of rupture or higher in case of only runouts than the previous load level. For example, if ruptures occur at 1 000 N, set the second load level to 500 N.

The AF/N diagram is generated as follows. In case of rupture before reaching $6{,}5 \times 10^6$ cycles, record the load level and the number of cycles. In case a sample survives $6{,}5 \times 10^6$ cycles, record the load level and mark as “runout”. Establish the new load levels until there is a tight range between only runouts and a higher load level with first ruptures. The range between these neighbouring load levels should be approximately 10 %.

The recommended maximum R-value for cyclic testing is 0,5 in order to increase comparability of different products. When choosing a lower R-value of e.g. 0,25 or 0,1, the amplitude becomes higher, possibly leading to earlier failure. This limits comparability but is deemed acceptable since a lower R-value is more challenging to the product. An R-value of >0,5 shall not be used.

The test may be driven in a constant load or a constant displacement mode. However, constant displacement testing should be performed only if the actual applied loads are measured continuously or at frequent points during the testing and the variation of the actual applied load is minimal. The minimal peak load applied during constant displacement testing shall be used to establish the endurance load level.

The recommended frequency to run the test is (3,33 ± 0,33) Hz. If an alternate frequency is used, sufficient justification shall be included.

The test shall either be performed at (23 ± 2) °C or at (37 ± 2) °C and a justification for the selected temperature shall be provided. When the sample is placed on the bottom plate at the beginning of each test, the highest point of the implant’s profile should be aligned with the compression load axis, i.e. the centre of the upper plate (see Figure C.5).

It is advisable to confirm there are no wrinkles or folds at the implant’s surface in contact with the bottom plate.

The test shall be performed as follows:

a) drive the actuator with the upper plate upwards in order to allow placement of the implant on the bottom plate without touching the upper plate;

b) place the implant on the bottom plate;

c) tare the load cell;

d) drive the actuator with the upper plate downwards and onto the implant until a certain preload is achieved, e.g. 10 N;

e) start the test by generating an alternating vertical motion of the mobile plate, either load-controlled or displacement-controlled;

f) the test shall proceed for a minimum of $6{,}5 \times 10^6$ cycles;

g) in case of rupture before reaching $6{,}5 \times 10^6$ cycles, record the load level and the number of cycles;

h) in case of runout over $6{,}5 \times 10^6$ cycles, record the load level and mark as “runout”;

i) every load level shall be repeated three times with new samples;

j) enter the results into the AF/N diagram.

C.3.5 Test report

The test report testing shall include at least the following:

a) a description of specimens, including the manufacturer's name, the model, the serial numbers or batch numbers;

b) a description of the test equipment, the testing temperature, the load or displacement control used, the number of runout cycles, the frequency used, as well as the *R*-value used;

c) the AF/N diagram;

d) the resulting endurance load level;

e) the raw data (e.g. applied loads, applied displacements) in terms of peak and valley load measurements;

f) a tabular representation including every sample tested: the peak and valley load, the result (rupture or runout) and the number of cycles until rupture or runout;

g) photographs of the samples after the test; in case of failure, a photograph of the sample should be taken inside the test setup;

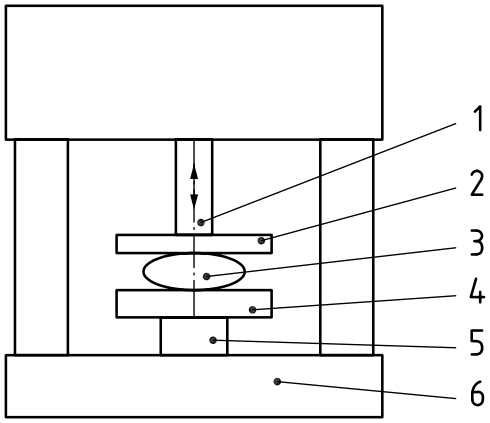
h) a reference to this document and to the method in Clause C.3, i.e. ISO 14607:2024, Clause C.3;

i) the testing date;

j) the identity of the responsible tester;

k) any deviations from the procedure;

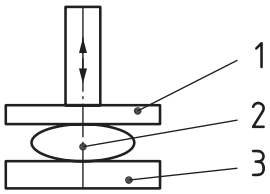
l) any unusual features observed.



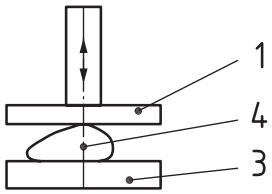
Key

1	actuator of universal testing machine equipped with displacement sensor	4	bottom plate
2	upper plate	5	load cell
3	implant specimen	6	load frame

Figure C.4 — Endurance load level test apparatus



a) Round implant



b) Anatomical implant

Key

1 upper plate
2 round implant aligned centrally with the load axis
3 bottom plate
4 anatomical implant: highest point of the implant's profile aligned centrally with the load axis

Figure C.5 — Alignment of the mammary implant between the plates: Round shape and anatomical shape

Annex D
(normative)

Tests of valve competence and injection site competence

D.1 Valve competence

D.1.1 Principle

This test method determines valve competence. This test shall only be carried out for inflatable implants.

D.1.2 Materials

Inflatable implant.

D.1.3 Procedure

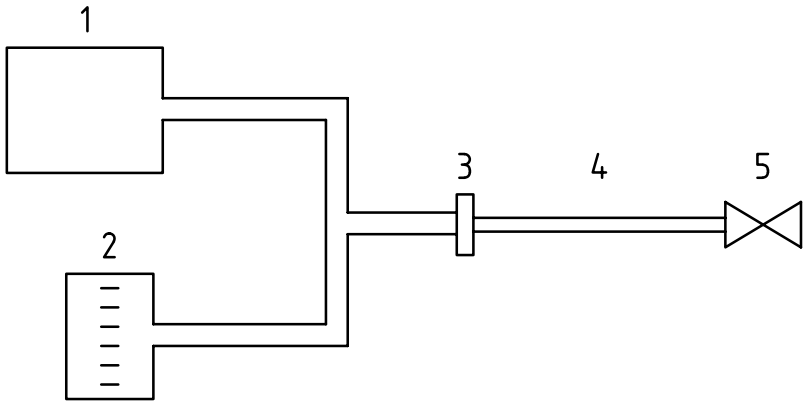
The valve shall be tested on an assembled implant as follows.

Prior to testing, manipulate the valve to simulate its use for filling an implant, as described in the instructions for use.

Apply an increasing retrograde pressure (pressure to the inner or lumen side of the valve) equivalent to (3,0 ± 0,3) kPa [approximately (300 ± 30) mm of water] using air, water or a test medium with demonstrated equivalence. Maintain this pressure for (5,0 ± 0,1) min. Figure D.1 shows a schematic assembly test system.

Examine the valve for leakage. When the test medium is air, immerse the valve in water to check for leaks (bubbles). If liquid test media are used, check for droplets that can emerge at the outer surface of the valve.

Reduce the pressure to the equivalent of (0,3 ± 0,1) kPa (approximately 30 mm water). Maintain at this pressure for (5,0 ± 0,1) min and check for leaks.



Key

1 pressure system
2 manometer
3 coupling device
4 implant lumen
5 implant valve

Figure D.1 — Schema of a testing system

Examine the valve for leakage. When the test medium is air, immerse the valve in water to check for leaks (bubbles). If liquid test media are used, check for droplets which can emerge at the outer surface of the valve.

D.1.4 Requirement

No leakage shall occur during both steps of high and low pressures.

D.2 Injection site competence

D.2.1 Principle

This test method determines injection site competence.

D.2.2 Materials

Use needles recommended by the manufacturer for normal use.

Use water or a test medium with demonstrated equivalence.

D.2.3 Procedure

The injection site of the assembled device shall be tested with needles recommended by the manufacturer for normal use.

Using water or a test medium with demonstrated equivalence, apply an intraluminal pressure of (3,0 ± 0,3) kPa [approximately (300 ± 30) mm of water].

Puncture the injection site for a total of five times at 1 min intervals within a 1 mm^2 area near the centre of the site.

Examine the injection site for leakage. When the test medium is air, immerse the site in water to check for leaks (bubbles). If liquid test media are used, check for droplets which can emerge at the outer surface of the site.

D.2.4 Requirements

The implant does not meet injection site leak requirements if droplets of fluid or bubbles appear, and continue to appear after 30 s, on the punctured surface.

D.3 Test report

In the test report, at least the following information shall be registered:

a) the sample size (number of mammary implants assessed);

b) a description of implant specimens, including manufacturer, model and serial number;

c) a reference to this document and to the method in Annex D, i.e. ISO 14607:2024, Annex D;

d) the date of the test;

e) the identity of the responsible tester;

f) the test method used, including any deviations from the procedure;

g) the test equipment used;

h) an indication of the valve competence or the injection site competence in accordance with D.1.4 or D.2.4, respectively;

i) any unusual features observed.

Annex E
(normative)

Test of silicone gel cohesion for silicone filling materials only

E.1 Principle

This test method determines the cohesion of the silicone gel.

E.2 Test specimens

A test specimen consists of silicone gel collected from an implant.

E.3 Apparatus

Test apparatus as shown in Figure E.1, internal volume (100 ± 5) ml.

The value of internal surface roughness, S_a, shall be the mean height of the profile below and above the line, as defined in ISO 21920-2.

E.4 Procedure

The test shall be performed at a temperature of (23 ± 2) °C, as follows.

a) Fill the apparatus with the gel.

   A representative test sample of the gel should be collected from a single implant of sufficient size to allow the gel to be removed as one cohesive mass.

   Care should be exercised when removing the gel and transferring it to the test fixture. Severe mixing, handling, air entrapment, etc. will produce erroneous results.

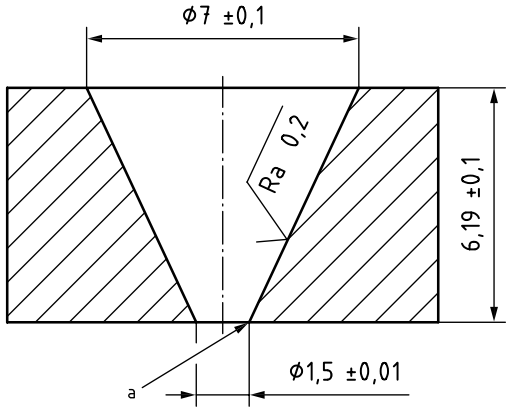
b) At the beginning of the test, the gel shall be flushed with the lower surface of the apparatus and shall be flushed with, or above, the top surface.

c) Allow the gel to flow unrestricted through the lower opening for (30,0 ± 0,1) min.

d) Note if any gel separates from the test volume.

e) Measure the projecting length of the gel.

Dimensions in centimetres,
value of surface roughness in micrometres



[a] Sharp angle.

Figure E.1 — Test of gel cohesion

E.5 Requirements

The test specimen meets the requirements of the test if there is no separation in the gel projection and the projecting length of the gel is less than or equal to 30 mm.

All of the test specimens shall fulfil this acceptance criteria.

E.6 Test report

In the test report, at least the following information shall be reported:

a) the sample size (number of test specimens assessed);

b) a description of the implants from which the test specimens are taken, including the manufacturer, the model and the serial number;

c) a reference to this document and to the method in Annex E, i.e. ISO 14607:2024, Annex E;

d) the date of the test;

e) the identity of the responsible tester;

f) the test method used, including any deviations from the procedure;

g) the test equipment used;

h) the test specimen performance result and the measurement of the projection length of the gel for each test specimen;

i) any unusual features observed.

Annex F
(normative)

Test of silicone gel penetration for silicone filling materials only

F.1 General

The penetration test is a quantitative determination of the firmness of gel used within the mammary implant. The test is based on examining the cured gel to verify adequacy of the mixing protocol and to verify intended mix ratios. The cure takes place within the test cup. A penetrometer method and an alternative texture analyser method are outlined in this annex. If other methods are used, they shall be validated to demonstrate equivalent accuracy to the methods in this annex.

F.2 Apparatus

F.2.1 Equipment for penetrometer procedure

F.2.1.1 Universal penetrometer, or equivalent (analogue or digital and capable of measuring to 0,1 mm), as shown in Figure F.1.

The mass of the penetrometer rod and foot should be within ±1 % from its specification.

F.2.1.2 Penetrometer foot and test cup, chosen to provide consistent results. The penetrometer foot size, the test cup size and the fill level shall be chosen to ensure that there is no impact of the test cup on test results. The radius of the foot shall be selected to ensure:

— a clearance of at least 1,3 cm from the internal wall of the test cup;

— that the test cup shall not overflow upon submergence of the foot;

— the bottom of the foot at maximum depth shall be at least 1,3 cm from the test cup base; and

— that no interaction between the foot and the test cup shall occur.

F.2.1.3 Balance.

F.2.1.4 Timer.

F.2.1.5 Isopropyl alcohol.

F.2.1.6 Foam wipe.

F.2.2 Equipment for texture analyser procedure

F.2.2.1 Texture analyser, as shown in Figure F.2.

F.2.2.2 Probe and penetration test cup, chosen to provide consistent results. The probe, the test cup size and the fill level shall be chosen to ensure that there is no impact of the cup on test results. They shall be selected to ensure:

— a clearance of at least 1,3 cm from internal wall of test cup;

— that the test cup shall not overflow upon submergence of the probe;

— that the bottom of the probe at maximum depth shall be at least 1,3 cm from the test cup base; and

— that interaction between the probe and the test cup shall not occur.

F.2.2.3 Balance.

F.2.2.4 Isopropyl alcohol.

F.2.2.5 Foam wipe.

F.3 Procedure

F.3.1 Test specimen preparation

F.3.1.1 At least three samples shall be taken from each raw material lot.

F.3.1.2 For each pair of sampled parts, mix both parts at the prescribed ratio to obtain the gel precursor mixture. De-air the gel precursor mixture.

F.3.1.3 Fill the test cup with the gel precursor mixture such that the test cup will not overflow when the foot or probe is submerged.

F.3.1.4 Cure each gel precursor mixture to obtain the gel test specimen.

F.3.1.5 Allow the gel test specimen to cool to room temperature prior to testing.

F.3.2 Penetrometer procedure

F.3.2.1 Clean specified penetrometer foot and shaft with isopropyl alcohol and foam wipe. Allow to dry at ambient conditions for a minimum of 5 min.

F.3.2.2 Place the gel test specimen in the centre of the penetrometer platform and under the penetrometer foot.

F.3.2.3 Zero the penetrometer depth gauge in accordance with equipment instructions.

F.3.2.4 Lower the rod and foot assembly over the test specimen so that the foot just touches the surface without making any indentations by handling it gently.

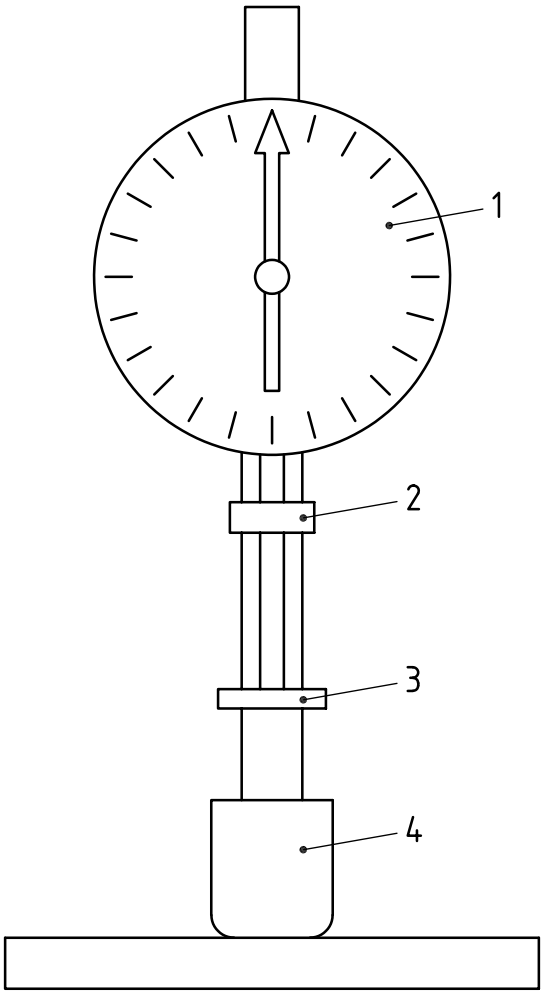
F.3.2.5 Simultaneously depress the timer start button and depress trigger of the penetrometer. Hold trigger down for the specified number of seconds and then rapidly release it. If not otherwise specified, the hold time is 5 s. During this time, the foot and rod have penetrated the test specimen.

NOTE Certain penetrometers are equipped with automated timing and penetrometer release mechanisms, thus negating the need for a separate timer or to physically depress the penetrometer release trigger.

F.3.2.6 Gently depress the depth gauge as far as it will travel. Record penetration result to the nearest 0,1 mm.

F.3.2.7 Repeat F.3.2.1 to F.3.2.6 using the remaining gel test specimens prepared from the other two samples (see F.3.1.1) ensuring to test only once per specimen.

F.3.2.8 Record the results and verify that the results from each test specimen meet the appropriate specifications (see 7.2.3.3.3) and vary less than 10 % from the median value. If the penetration for each replicate is within the appropriate specification, report the mean penetration.



Key

1	graduated scale	3	penetrometer foot
2	release button	4	test cup

Figure F.1 — Penetrometer diagram

F.3.3 Texture analyser procedure

F.3.3.1 Turn on the texture analyser in accordance with equipment instructions.

F.3.3.2 Calibrate the texture analyser in accordance with equipment instructions. The force employed for testing shall be within the calibrated range of the load cell. The force to be used shall be chosen depending on the suitability of the force for measurement of the gel.

F.3.3.3 Load specified the test program from the texture analyser software program.

F.3.3.4 Clean the specified texture analyser probe with isopropyl alcohol and a foam wipe. Allow to dry at ambient conditions for a minimum of 5 min.

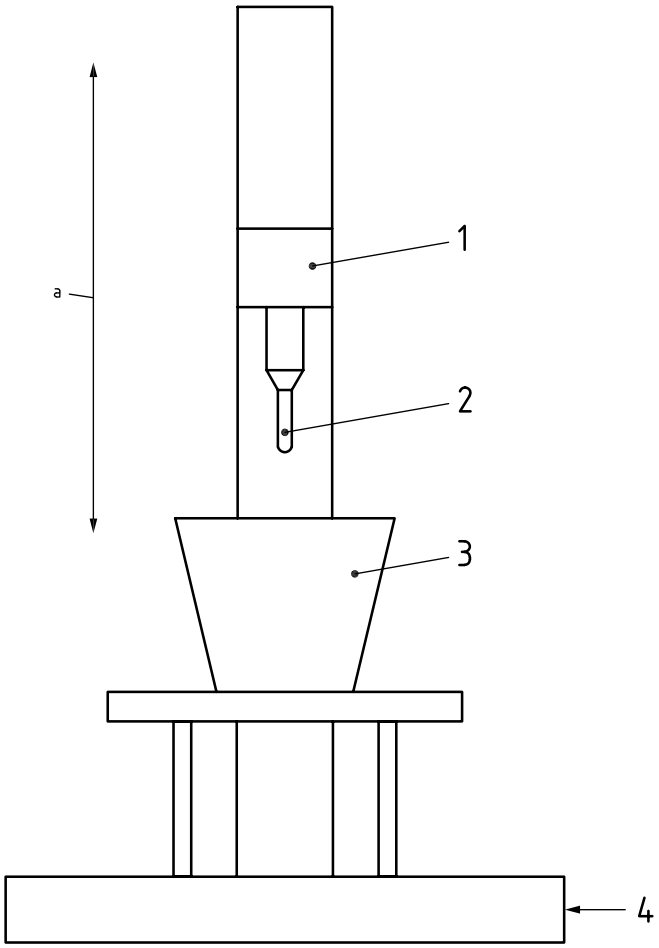
F.3.3.5 Place the cured gel test specimen in the centre of the texture analyser platform and under the texture analyser probe.

F.3.3.6 Lower the texture analyser probe until it is approximately 1 cm above cured gel surface.

F.3.3.7 Test in accordance with equipment instructions.

F.3.3.8 Repeat F.3.3.4 to F.3.3.7 using the remaining gel test specimens prepared from the other two parts samples (see F.3.1.1) ensuring to test only once per specimen.

F.3.3.9 Record the results and verify the results from each test specimen meet the appropriate specifications (see 7.2.3.3.3) and vary less than 10 % from the median value. If the penetration for each replicate is within the appropriate specification, report the mean penetration.



Key

1	penetrometer head	3	sample cup
2	penetrometer probe	4	base
a	Direction of movement.		

Figure F.2 — Texture analyser diagram

F.4 Remark

The gel penetrometer results are valid only for comparisons within a manufacturer's product line. They are not valid for comparisons between manufacturers as slightly different test method or test apparatus can provide different results.

F.5 Test report

In the test report, at least the following information shall be reported:

a) the date of the test;

b) the identity of the person that performed the test;

c) a reference to this document, i.e. ISO 14607:2024;

d) a reference to the test method used (either F.3.2 or F.3.3);

e) a description of the sampled materials used to prepare the test specimens, including lot identification;

f) a description of the test equipment;

g) the texture analyser's settings used for the test if the texture analyser is used;

h) the specification or acceptance criteria against which the test is evaluated;

i) the gel test specimen penetration results;

j) any deviations from the procedure;

k) any unusual features observed.

Annex G
(normative)

Surface classification

G.1 Principle

Surface texture is an important characteristic of mammary implants and is associated with their performance and safety.

G.2 Materials

Mammary implant elastomer shells of finished devices.

Alternatively, mammary implant elastomer shells without filling may be used, if the shells went through all steps of the manufacturing process except the filling process.

G.3 Method

The characteristics of the shell surface shall be recorded by an appropriate surface metrology system. Two surface characteristics are used as part of the classification of the mammary implant:

a) the arithmetical mean height of the scale-limited surface, or average surface roughness, S_a, as defined in ISO 25178-2;

b) the surface complexity, S_{cx}, provides a measure of the tortuosity of the surface and considers overhanging and hidden structures. It is defined according to Formula (G.1) and illustrated in Figure G.1.

$$S_{cx} = \frac{l_A}{l_S} - 1 \tag{G.1}$$

where

S_{cx} is the surface complexity;

l_A is the actual length between two points on the surface, in mm;

l_S is the length of a straight line between two points on the surface, in mm;

NOTE 1 Surface complexity is estimated from a 2D cross-section of the shell but ultimately provides a measure of added surface area compared to a surface with a surface complexity of 0.

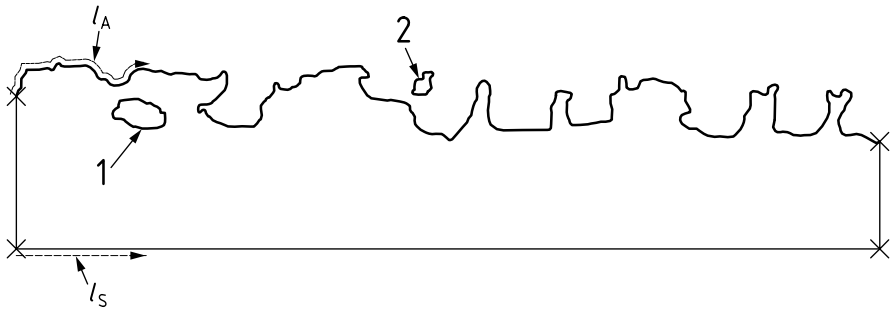
Resolution of the measurement method should be at least 1 000 pixels for 2 mm (or 2 µm/pixel) laterally (X-Y directions) (see ISO 25178-3) and 2 µm/pixel vertically (Z direction) or better. The methods and post-processing steps used for the measurement can affect the results of S_a and S_{cx}. Therefore, adequate information on methods and post-processing used shall be reported to give context to the results. In particular, the use of form correction, optical, mathematical or other filters should be justified and validated.

To measure S_a, surface imaging shall be performed using a method that allows metrology in three dimensions. A surface depth map shall be constructed from the 3D surface mesh by assigning the highest measured Z-value to each measured X-Y coordinate of the surface. Measurements shall be performed using validated methods to determine S_a from the surface depth map. With the exception of micro computed tomography (micro-CT), image acquisition should be taken from above and perpendicular to the surface.

To measure S_{cx}, the image acquisition shall be taken from the side, perpendicular to the cut made in the shell. Focus depth of the field shall be 100 µm or less in order to sample only the features present at the cut line. Islands and voids are to be ignored, see Figure G.1.

If the surface texture is intentionally designed to be different in different directions (i.e. anisotropic), then multiple cut planes shall be used. Each cut plane shall correspond to those intended different direction(s) of texture. The value of the cut plane with the highest surface complexity shall be reported.

Micro-CT can perform virtual cuts and therefore should be set up in a way that mimics the results that would be achieved by an optical system with actual cuts. Slice width for S_{cx} shall be less than 100 µm.



Key

l_A actual length between two points on the surface (mm)

l_S length of a straight line between two points on the surface (mm)

1 void

2 island

Figure G.1 — Schema of a cross-section view of the textured shell with examples of island and void

NOTE 2 Examples of suitable image acquisition techniques are laser scanning microscopy, white-light interferometry, digital optical microscopy, optical profilometry, X-ray micro-CT or scanning electron microscopy (SEM).

NOTE 3 Other characteristics can be recorded such as the presence of pores or voids on the surface, pore size or diameter (porosity), number and height of peaks and resulting kurtosis, number and depth of valleys and resulting skewness, average distance between morphological features, mean peak height, room mean square roughness, maximum peak height, waviness, stiffness or hardness, coefficient of friction (shell material against itself), and wettability.

G.4 Test specimen preparation

G.4.1 General

Specimens from the sample shell shall be taken, using Figure G.2 as a guide for the base and anterior surfaces. The diagram represents one shell. Three representative shells shall be measured. This represents five test specimens cut from each shell (two from the anterior surface and three from the base surface), with a total of 15 test specimens. This shall be conducted for each surface type.

Each test specimen shall be labelled properly, including the area on the shell where specimens were taken, to avoid any confusion or misplacement.

The test specimen may be cleaned, with a non-damaging volatile fluid, such as isopropanol or ethanol, to eliminate all possible contaminants without damaging the surface. Handling and storing of test specimen shall be made appropriately in order to avoid dust contamination.

Further preparation shall be suitable for the test specimen required by the corresponding apparatus and the procedure shall be recorded.

G.4.2 Average surface roughness of the specimen preparation

The average roughness, S_a, shall be measured over areas of (4,0 ± 0,1) mm^2.

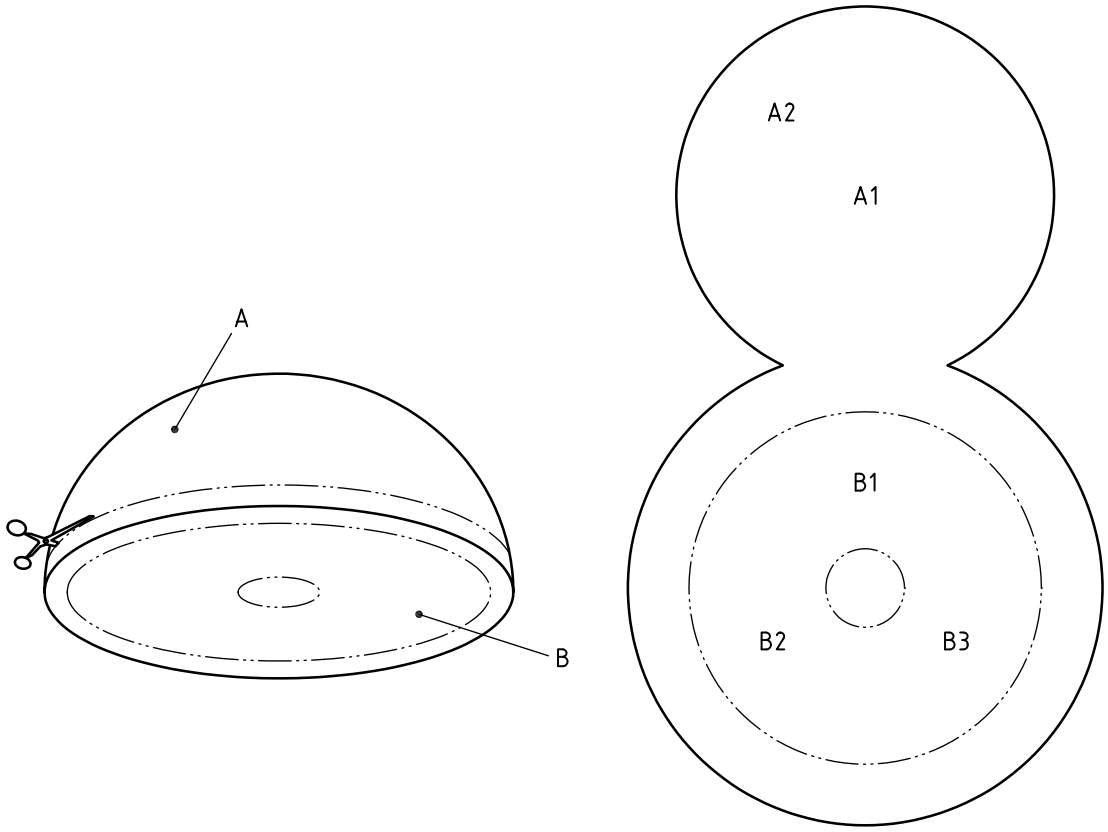
G.4.3 Surface complexity of the specimen preparation

The specimens shall have a minimum length of (4,0 ± 0,1) mm and with a clean, straight cut that is perpendicular to the surface.

A cutting die should be used to achieve the desired cut, for example die Type 2, as detailed in ISO 37. Other cutting methods are acceptable.

With proper handling, the same specimens may be used for S_a and S_{cx} measurements.

Measurements of surface profiles should not be performed immediately after the cross-sectioning in order to avoid time- and strain-dependent viscoelastic responses to the forces induced by the cutting device. In order to minimize the influence of these effects on the measurements, a minimum time window of 1 h should be kept between the cut and the profile acquisition.



Key

A anterior surface

B base surface

NOTE The outer surface must be facing upwards.

Figure G.2 — Surface locations from one shell dissected close to the base

G.5 Expression of results

G.5.1 General

Due to the high levels of surface texture scrutiny from surgeons, patients and health authorities, it is important that measurements made at different times, on different devices and by different laboratories be comparable. The surface classification shall be standardized in order to facilitate the analysis of patient data.

The classification scheme is based on a multipolar system incorporating parameters summarized in Table G.2.

G.5.2 Implant surface finish technique

Three categories of surface finish techniques of the outer surface of the implant are considered:

— no intentional texturization (NTX);

— additional shell surface coating layers, which include but are not limited to:

  — polyurethane foam layer (PUL);

  — other material layer (OML);

— intentionally textured silicone shell surfaces, which include but are not limited to:

  — salt loss – closed (SLC): salt, usually sodium chloride, is applied to uncured silicone and an extra layer of uncured silicone is applied over the salt which is abraded after curing to remove the salt;

  — salt loss – open (SLO): salt, usually sodium chloride, is applied to uncured silicone and the salt is washed away after curing;

  — other crystal loss – closed (CRC): as for salt loss closed, but with another crystal;

  — other crystal loss – open (CRO): as for salt loss open, but with another crystal;

  — gas diffusion – sub-surface (GDD): ammonium carbonate is embedded in the silicone and the gases bubble through the uncured silicone during curing;

  — gas diffusion – surface (GDS): ammonium carbonate is on the surface of the silicone and leaves grain-shaped openings on the silicone surface when it thermally decomposes during curing;

  — polyurethane imprinting (PUI): polyurethane is pressed onto the uncured silicone and removed before curing;

  — mandrel imprinting (MAI): the texture of the mandrel is transferred to the silicone during curing (shell turned inside out); and

  — other technique (OTH).

If the implant has multiple different surfaces (e.g. base and anterior surface), all surface finish techniques shall be reported (e.g. PUL/SLO).

For surfaces manufactured with a polyurethane foam layer, no surface roughness value shall be measured or reported (see G.5.6).

For surfaces manufactured with an OML, the average surface roughness, S_a, shall be measured and reported. If this is not an appropriate parameter for the particular material layer, the manufacturer shall use a different, appropriate parameter and justify this. This can be the same parameter as for the polyurethane foam layer (see G.5.6), or a different parameter.

G.5.3 Averaging technique for surface characterization

Surface parameters include surface roughness, surface complexity and porosity as applicable.

The surface parameter of the base and anterior surfaces of the finished product shall be measured in accordance with Clause G.4.

The surface area of the base and anterior surfaces of the finished product shall be determined.

The mean values are first formed separately for the base and the anterior surface over the three measured samples, then the following procedure is followed for the surface parameters.

— If one of the average surface parameter values is more than 20 % larger than the other average surface parameter value, the larger average surface parameter value shall be reported.

— If none of the average surface parameter values is more than 20 % larger than the other average surface value, a weighted overall average surface parameter value shall be calculated as defined by Formula (G.2) and shall be reported.

Formula (G.2) represents an example for the parameter “average surface roughness”. Equivalent calculations shall be applied for other parameters.

$$S_a = \frac{A_A S_{a,A} + A_B S_{a,B}}{A_A + A_B} \quad \text{(G.2)}$$

where

S_a is the weighted overall average surface roughness of the implant, in µm;

A_A is the anterior surface of the implant, in mm^2;

A_B is the base surface of the implant, in mm^2;

$S_{a,A}$ is the average anterior surface roughness of the implant, in µm;

$S_{a,B}$ is the average base surface roughness of the implant, in µm.

G.5.4 Average surface roughness of the threshold

For intentionally textured surfaces, the grade in accordance with Table G.1 shall be reported in addition to the calculated average surface roughness value (either the larger average surface roughness value or the weighted overall average surface roughness of the implant, S_a).

Table G.1 — Grading of surface roughness

S_a µm	Grade
<50	micro-textured
≥50	macro-textured
NOTE The surface roughness thresholds were based on extensive data collection by the Therapeutic Goods Administration[5] and a review of the literature (e.g. References [6], [7] and [8]). While the 50 µm threshold delineates the categories of micro-textured and macro-textured, there can be a range of clinical outcomes within each category.	

G.5.5 Surface complexity

As it is intended to collect surface complexity data and possible correlations with clinical outcomes, no grading of surface complexity has been introduced.

G.5.6 Average pore size

For surfaces manufactured with a polyurethane foam layer, the average pore size shall be measured and reported instead of the surface roughness and surface complexity.

NOTE 1 Since surfaces manufactured with a polyurethane foam layer are not two-dimensional in nature, they are not well represented by 2D characterization techniques. The three-dimensional measure average pore size is measured and reported instead of surface roughness and surface complexity.

NOTE 2 Light microscopy is one suitable method to measure the average pore size.

G.5.7 Summary of reported parameters

See Table G.2 for an overview of parameters to be reported. Cells marked with "x" indicate which parameters are reported for the specific surface finish technique.

Table G.2 — Summary of reported parameters for surface classification

Surface finish technique	Roughness grade	Average surface roughness S_a	Surface complexity S_{cx}	Average pore size P
NTX	—	x	x	—
SLC, SLO, CRC, CRO, GDD, GDS, PUI, MAI, OTH	micro-textured (<50)	x	x	—
	macro-textured (≥50)			
PUL	—	—	—	x
OML	The requirements depend on the specific material layer used (see G.5.2 for details).			
NOTE It is acknowledged that the value of one surface parameter is not likely to be fully responsible for clinical outcomes. The collection of data on the surface parameters in this table will allow research to further study the relationship between surface parameters and clinical outcomes.				

G.6 Test report

In the test report, at least the following information shall be reported:

a) the date of the test;

b) the identity of the responsible tester;

c) the sample size (number of mammary implants assessed);

d) a description of sampled mammary implant, including manufacturer, model, serial numbers or lot code;

e) a detailed description of methods used to obtain relevant surface parameter(s);

f) all individual results and analysis from each test specimen for the relevant surface parameter(s);

g) the surface classification in accordance with Table G.2, including surface parameter(s), their mean values and standard deviations;

h) any images presented in the report should have a scale bar;

i) any test equipment used;

j) any deviations from the procedure;

k) any unusual features observed;

l) a reference to this document, i.e. ISO 14607:2024.

Annex H
(normative)

Information for the user

H.1 General

The requirements of ISO 14630:2024, 11.4 shall apply. In addition, Clauses H.2 to H.10 shall be included.

H.2 Surface classification

Include a description of the implant with its surface classification in accordance with Table G.2.

H.3 Filling materials

For inflatable and adjustable implants, the manufacturer shall indicate the filling materials and filling instructions.

H.4 Overall qualitative and quantitative composition of the implant

It shall include a detailed qualitative and quantitative description of the materials of construction of the breast implant, with tables listing breast implant materials, chemical components and heavy metals present in breast implants.

H.5 Resterilization

The requirements of ISO 14630:2024, 9.3, shall apply.

H.6 Effects on diagnostic techniques

The effect of the implant on diagnostic techniques, such as mammography or magnetic resonance imaging (MRI), shall be provided to the user.

H.7 Precautions

The following precautions shall be included in the instructions for use:

— precautions for the surgery;

— precautions regarding the use of closed capsulotomy;

— instructions and precautions for removal.

H.8 Implant card and patient information brochure

Add a statement requiring the surgeon to ensure that the patient will receive the minimum information described in 11.8, provided by the manufacturer.

The instructions relating to the implant card shall include:

— a reminder to check its availability;

— a statement that the implant card belongs to the patient and it is the responsibility of the user to provide it to the patient.

H.9 Recommended surgical techniques

Where relevant, the location and recommended techniques for use shall be clearly described.

Where relevant, the recommended techniques with respect to correct orientation of the implant shall be clearly described.

Where relevant, if further surgical procedures/interventions are required for the intended use of the implant (e.g. to locate a port for inflation), the recommended techniques shall be clearly described.

Where relevant, the potential complications associated with implantation and their possible intraoperative resolution shall be included.

H.10 Other information for the user

The following information shall also be provided to the user:

— recommendations for medical follow-up;

— expected lifetime, expressed in accordance with 11.7;

— potential complications and their possible resolutions.

Annex I
(normative)

Patient information brochure

The information contained within this annex shall be provided in a manner and format that is easily accessible to patients.

The patient information brochure shall include:

a) the name (and if applicable, trade or commercial name) and the address of the manufacturer;

b) a description of the implant, including

- the type;
- the materials of construction of the implant in a language that is understandable to the patient (e.g. silicone);
- the principles of operation (e.g. prefilled or inflatable implant);
- the chemical components, provided in a table, listing breast implant materials, chemicals that can be released from breast implants and heavy metals present in breast implants. The brochure shall provide context to the levels of risk of or exposure to the chemicals and heavy metals listed in this table. For example, manufacturers can observe that the potential toxicity of the chemicals and metals have been evaluated through toxicity testing and risk assessments to assess the exposure levels in comparison to the amount determined to likely be safe, but that individual responses can vary and that all reactions cannot be predicted.

  NOTE An example is described in Annex C of Reference [9].

- a description of the implant including its surface classification in accordance with Table G.2;
- the shape;
- the range of implant volumes available;
- the range of implant weight available;
- where relevant, any other characteristics of the implant;

c) the intended use of the device;

d) the expected lifetime of the implant, expressed in accordance with 11.6, with a note to indicate expected lifetime is not a guarantee of lifetime of the device;

e) the following warnings:

- “Mammary implants have a limited lifetime”;
- “This implant can require removal or replacement, which is classified as revision surgery”;
- any other warnings, precautions or measures to be taken by the patient or user;

f) the anticipated benefits;

g) a list of all residual risks, potential harm and adverse effects including those commonly related to surgery and the implant, and an indication of the expected rate of occurrence. The information shall include an indication to seek medical advice when appropriate and the list shall include at least the

following potential risks and complications, and any other potential risks and complications identified by the manufacturer:

- infection;
- risks associated with the procedure, such as bleeding, embolism, post-operative swelling, death;
- a statement “The chance of developing complications increases over time; some complications can require more surgery”;
- risk of permanent pain;
- unexpected or recurrent fluid collection around the implant, e.g. seroma;
- a statement that breast implants have been associated with the development of a cancer of the immune system called IA-ALCL;
- systemic symptoms associated with breast implants sometimes referred to as ‘breast implant illness’;
- tissue necrosis;
- migration of the implant;
- rupture within and outside the capsule, including the possibility of “silent” rupture;
- leakage of the contents of the implant following shell rupture;
- development of siliconomas in the breast, armpit or elsewhere in the body following migration of the contents of the shell;
- deflation;
- wrinkling;
- capsular contracture;
- gel bleed;
- suture tab breakage (if applicable);

h) the possible effects of the implant on breastfeeding;

i) the need to consult a surgeon for medical follow-up;

j) the need to consult a physician or a pharmacist before the use of topical medicines (e.g. steroids) in the breast area;

k) the need to continue to consult a physician to carry out normal checks in order to detect breast cancer;

l) effects of the implant on diagnostic techniques, such as mammography, biopsies or aspirations; a statement shall be included to indicate that the presence of breast implants can make it more difficult to detect suspicious abnormalities in the breast;

m) if applicable, a statement regarding the presence of metallic components within the implant e.g. RFID chips and any potential impact on future imaging;

n) where appropriate, a statement concerning the safety of the implant in the magnetic resonance environment;

o) the need to inform the radiologist if a mammography is carried out in order to adapt the mammographic compression;

p) the possible effects of the implant on auto-palpation;

q) an indication that any implant inserted into the human body will cause an immunological reaction and this can vary from patient to patient and can become clinically significant in some patients;

r) an indication that the patient should consult a physician if the patient suspects any complications, particularly in the case of trauma or compression caused, for example, by some sport activities or the use of seat belts;

s) an indication that after consultation with their physician, it is encouraged to report the suspected complication to either the manufacturer or the relevant regulatory authority, or both;

t) the recommendation to patients that, to facilitate medical care, they always carry the implant card in case of an emergency.

The patient information brochure shall be reviewed and updated regularly as additional data are collected with post-market experience. A link to a dedicated easily accessible webpage shall be provided for each device that allows providers involved in the care of breast implant patients and patients with specific breast implants to regularly monitor changes to the patient brochure.

Annex J
(normative)

Tests of surface particulate contamination

J.1 Principle

The test methods specified in this annex determine the quantity, size, morphology and chemical identification of the particulate contamination on the implant surface.

Whenever a change is introduced (e.g. to the manufacturing process or the manufacturing environment) which can affect particulate contamination, any potential sources for particulate contamination shall be considered and evaluated within the risk management process.

Possible sources for particulate contamination shall be identified, assessed and evaluated within the risk management process. The results shall be documented.

EXAMPLE Potential sources are:

— gowning and clothing;

— particles originating from the manufacturing process, surface finishing, implant material, equipment and/or tools;

— paper used to record production information.

As stated in 7.2.3.8, a frequency of periodic testing shall be established for each of the tests for surface contamination, including the methods outlined in Annex J.

J.2 General

Sampling of devices for tests on particulate contamination shall be done in accordance with a risk-based approach, considering possible sources of particles in the manufacturing process and environment as well as variability between shifts and batches.

J.3 Test sample

Any test samples shall be taken from sterile mammary implants within their sterile barrier system.

J.4 Rinsing method

J.4.1 General

The test samples shall be submitted to a clean environment for processing.

The test should be carried out under conditions limiting process or product unrelated particulate contamination, preferably in a clean room or a laminar flow cabinet.

J.4.2 Test preparation

Separate tests shall be prepared by rinsing different test samples with two different particle-free solvents [particle-free water and particle-free ethanol or isopropanol with a purity of at least 99,5 %].

a) Obtain clean certified glassware or rinse in-house glassware prior to rinsing the product sample. In case of using in-house glassware, rinse the glassware until an acceptable particle count is reached.

b) Partially open the sterile packaging and add a small quantity of particle-free solvent and gently agitate.

c) Open the packaging and transfer the implant and the solvent to the clean beaker. Rinse the packaging with additional particle-free solvent and ensure all liquid is transferred to the beaker.

d) The size of the beaker shall be chosen to minimize the total amount of particle-free solvent being used and to allow free movement of the implant.

e) Fill with particle-free solvent enough to entirely submerge the device sample. Some implants can require submerging.

f) Note the total quantity of particle-free solvent used per implant.

g) Agitate the beaker. The time and speed for the agitation shall be documented as part of the test method validation.

J.4.3 Particle count methods

J.4.3.1 Light obscuration count method

For the light obscuration count method:

a) following agitation, immediately swirl and pour at least 100 ml of the solvent into a measurement vessel rinsed with particle-free solvent;

b) prepare the sample in accordance with the instrument instructions to ensure particles are uniformly distributed; efforts should be made to reduce aggregation and agglomeration;

c) run the light obscuration (LO) measurements;

d) record particulate count in two different intervals:

   1) 10 µm ≤ x ≤ 25 µm; and

   2) ≥25 µm.

J.4.3.2 Microscopic evaluation of the particulate contamination

For microscopic evaluation, a separate filter shall be used for each product sample.

For the microscopic count method:

a) remove the product sample and filter the rinsed solution;

b) add particle-free solvent to rinse the beaker and funnel of the filtration apparatus;

c) perform particle count by examination of the filters using a microscope with a calibrated scale;

d) for each filter sample, perform microscopic counting for particle shape and morphology with particle sizes reported in two intervals:

   1) 10 µm ≤ x ≤ 25 µm; and

   2) ≥25 µm;

e) record particulate matter shapes, morphologies and counts for further evaluation and trending.

NOTE ISO 26824 can be of assistance in characterizing particles.

J.5 Tape lift method

J.5.1 General

The test samples shall be submitted to a clean environment for processing.

The test should be carried out under conditions limiting process or product unrelated particulate contamination, preferably in a clean room or a laminar flow cabinet.

J.5.2 Test preparation

For the test preparation:

a) attach adhesive coated carbon tabs to SEM sample holders;

b) press the sample holders with adhesive tabs firmly against the surface of the implant at 50 locations that are representative of the entire implant surface; ensure that there are sample holders with adhesive carbon coated tabs are used as controls to determine background levels of particulates.

NOTE Using the tape lift method will only investigate the part of the surface to which the tape is applied. However, investigation of the morphology of soluble particles is only possible with the tape lift method.

J.5.3 Microscopic evaluation and chemical identification of the particulate contamination

For microscopic evaluation and chemical identification of the particulate contamination:

a) evaluate the particles of different shapes, morphologies, colour etc.;

b) for chemical evaluation particles, choose from possible different origins (e.g. different shapes, morphologies);

c) select three particles from each group for evaluation;

d) for each selected particle or fibre, perform analysis using suitable spectroscopic methods.

Care should be taken to trace the selected particles when transferring test samples between instruments.

NOTE 1 Raman spectro-microscopy, Fourier transform infrared (FTIR) micro-spectroscopy and scanning electron microscopy/energy dispersive X-ray spectroscopy (SEM-EDS) are some suitable methods. Additional information on spectroscopic method can be found in ISO 10993-18.

NOTE 2 Morphological properties of the tape can be falsely identified as particles when automatic particle detection by software is applied.

J.6 Test report

The test report shall include at least the following:

a) the date of the test;

b) the identity of the responsible tester;

c) the sample size (number of mammary implants assessed);

d) a description of the sampled mammary implant, including the manufacturer, model, serial numbers or lot code;

e) the surface classification of sampled mammary implant in accordance with Table G.2;

f) the test method used, including any deviations from the procedure;

g) the test equipment settings and calibration status;

h) the test results including the particulate matter count, morphology categories (fibre, irregular shape) and identification;

i) where limits are specified by the manufacturer, these should be documented; it shall also be documented if the test results are within the pre-specified acceptable limits.

j) a reference to this document, i.e. ISO 14607:2024;

j) any deviations from the procedure;

k) any unusual features observed.

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