

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Intended performance
5	Design attributes
6	Materials
6.1	General
6.2	Cytotoxicity
6.3	Residual low molecular weight oligomers
6.4	Trace elements
6.5	Physico-mechanical properties and characterization
6.6	Documentation of materials
7	Design evaluation
7.1	General
7.2	Pre-clinical evaluation
7.2.1	General
7.2.2	Mechanical tests
7.2.2.1	Shell integrity
7.2.2.1.1	General
7.2.2.1.2	Elongation
7.2.2.1.3	Tensile set
7.2.2.1.4	Strength of joints, seams or seals
7.2.2.2	Implant resistance
7.2.2.2.1	Fatigue resistance test
7.2.2.2.2	Impact resistance test
7.2.3	Physical evaluation
7.2.3.1	Design of shell
7.2.3.2	Valve or injection site competence
7.2.3.3	Filling material
7.2.3.3.1	General
7.2.3.3.2	Silicone gel cohesion
7.2.3.3.3	Silicone gel penetration
7.2.3.4	Diffusion test
7.2.3.5	Volume
7.2.3.6	Dimensions
7.2.3.7	Surface
7.2.3.8	Surface contamination
7.2.4	Chemical evaluation
7.2.5	Biological evaluation
7.3	Clinical evaluation
7.4	Post-market surveillance
8	Manufacturing

- 9 Sterilization
- 10 Packaging
- 11 Information supplied by the manufacturer

- 11.1 General
- 11.2 Product labelling
- 11.3 Information for the user
- 11.3.1 General
- 11.3.2 Resterilization
- 11.3.3 Effects on diagnostic techniques
- 11.4 Marking on implants
- 11.5 Filling materials
- 11.6 Information on expected lifetime
- 11.7 Information for the patient
- 11.7.1 General
- 11.7.2 Patient record label
- 11.7.3 Patient card

Annex A (normative) Determination of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in silicone gels

- A.1 Objective
- A.2 Principle
- A.3 Test specimen preparation
- A.4 Reagents
- A.5 Apparatus
- A.6 Experimental precautions
- A.7 Procedure
- A.7.1 Number of experiments
- A.7.2 Preparation of calibration standards and construction of calibration curves
- A.7.3 Test specimen analysis
- A.8 Calculation
- A.9 Specification
- A.10 Analytical validation
- A.11 Test report

Annex B (normative) Tests for shell integrity

- B.1 Shell material
- B.1.1 Test specimen preparation
- B.1.2 Elongation
- B.1.3 Tensile set
- B.2 Strength of seams
- B.2.1 General
- B.2.2 Critical seams
- B.2.3 Non-critical seams
- B.3 Test report

Annex C (normative) Mechanical tests on a mammary implant in its implantable state

- C.1 Fatigue test
- C.1.1 Principle
- C.1.2 Materials
- C.1.3 Apparatus
- C.1.4 Procedure
- C.1.5 Requirements
- C.1.6 Test report
- C.2 Impact resistance test
- C.2.1 Principle
- C.2.2 Apparatus
- C.2.3 Procedure
- C.2.4 Requirement
- C.2.5 Test report

Annex D (normative) Test method for valve competence and injection site competence

- D.1 Valve competence
- D.1.1 Principle
- D.1.2 Materials
- D.1.3 Procedure
- D.1.4 Requirement
- D.2 Injection site competence
- D.2.1 Principle
- D.2.2 Materials
- D.2.3 Procedure
- D.2.4 Requirements
- D.3 Test report

Annex E (normative) Test for silicone gel cohesion (silicone filling materials only)

- E.1 Principle
- E.2 Materials
- E.3 Apparatus
- E.4 Procedure
- E.5 Requirements
- E.6 Test report

Annex F (normative) Test for silicone gel penetration (silicone filling materials only)

- F.1 General
- F.2 Apparatus
- F.3 Procedure
- F.3.1 Test specimen preparation
- F.3.2 Penetrometer procedure
- F.3.3 Procedure for texture analyser
- F.4 Remarks
- F.5 Test report

Annex G (informative) Assessment of silicone diffusion from mammary implants using an in vitro method

- G.1 Principle
- G.2 Material and apparatus
- G.2.1 General
- G.2.2 Sampling preparation
- G.2.3 Simulated body fluid (SBF)
- G.2.4 SBF preparation
- G.2.5 Material preparation
- G.3 Procedure
- G.3.1 General
- G.3.2 Condition of release determination and Si measurements
- G.3.3 Expression of the results

Annex H (informative) Test for surface characteristics

- H.1 Principle
- H.2 Materials
- H.3 Apparatus
- H.3.1 General
- H.3.2 Surface metrology
- H.3.3 Surface topography imaging
- H.4 Test specimen preparation
- H.5 Data to be recorded
- H.6 Expression of results
- H.7 Test report

Annex I (normative) Information for the user

Annex J (normative) Information for the patient