

DIN EN ISO 14607:2018-10 (E)

Non-active surgical implants - Mammary implants - Particular requirements (ISO 14607:2018, Corrected version 2018-08)

Contents		Page
European foreword		4
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] aimed to be covered		6
Foreword		9
Introduction		11
1	Scope	12
2	Normative references	12
3	Terms and definitions	12
4	Intended performance	14
5	Design attributes	14
6	Materials	14
6.1	General.....	14
6.2	Cytotoxicity.....	15
6.3	Residual low molecular weight oligomers.....	15
6.4	Trace elements.....	15
6.5	Physico-mechanical properties and characterization.....	15
6.6	Documentation of materials.....	15
7	Design evaluation	16
7.1	General.....	16
7.2	Pre-clinical evaluation.....	16
7.2.1	General.....	16
7.2.2	Mechanical tests.....	16
7.2.3	Physical evaluation.....	17
7.2.4	Chemical evaluation.....	18
7.2.5	Biological evaluation.....	18
7.3	Clinical evaluation.....	18
7.4	Post-market surveillance.....	18
8	Manufacturing	18
9	Sterilization	18
10	Packaging	18
11	Information supplied by the manufacturer	19
11.1	General.....	19
11.2	Product labelling.....	19
11.3	Information for the user.....	19
11.3.1	General.....	19
11.3.2	Resterilization.....	19
11.3.3	Effects on diagnostic techniques.....	19
11.4	Marking on implants.....	19
11.5	Filling materials.....	19
11.6	Information on expected lifetime.....	19
11.7	Information for the patient.....	20
11.7.1	General.....	20
11.7.2	Patient record label.....	20
11.7.3	Patient card.....	20

Annex A (normative) Determination of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in silicone gels	21
Annex B (normative) Tests for shell integrity	24
Annex C (normative) Mechanical tests on a mammary implant in its implantable state	27
Annex D (normative) Test method for valve competence and injection site competence	33
Annex E (normative) Test for silicone gel cohesion (silicone filling materials only)	35
Annex F (normative) Test for silicone gel penetration (silicone filling materials only)	37
Annex G (informative) Assessment of silicone diffusion from mammary implants using an in vitro method	42
Annex H (informative) Test for surface characteristics	46
Annex I (normative) Information for the user	49
Annex J (normative) Information for the patient	50
Bibliography	51