

ISO 14607:2007-02 (E)

Non-active surgical implants - Mammary implants - Particular requirements

Contents		Page
Foreword		iv
Introduction		v
1 Scope		1
2 Normative references		1
3 Terms and definitions		1
4 Intended performance		2
5 Design attributes		2
6 Materials		3
7 Design evaluation		3
7.1 General		3
7.2 Pre-clinical evaluation		3
7.3 Clinical evaluation		6
7.4 Post-market surveillance		7
8 Manufacturing		7
9 Sterilization		7
10 Packaging		7
11 Information supplied by the manufacturer		7
11.1 General		7
11.2 Resterilization		8
11.3 Base dimensions		8
11.4 Effects on diagnostic techniques		8
11.5 Filling materials		8
11.6 Information on expected lifetime		8
11.7 Information for the patient		8
11.8 Labels		9
11.9 Information for the user		9
11.10 Marking on implants		9
11.11 Manufacturer's device card		9
Annex A (normative) Test for surface characteristics		10
Annex B (normative) Tests for shell integrity		11
Annex C (normative) Test method for valve competence and injection site competence		13
Annex D (normative) Test for silicone gel cohesion (silicone filling materials only)		15
Annex E (normative) Mechanical tests on a mammary implant in its implantable state		17
Annex F (normative) Information for the patient		22
Annex G (normative) Information for the user		24
Annex H (informative) Silicone release assessment from mammary implants by an in vitro method		25
Bibliography		28