

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