

# ISO 14602:2010-04 (E)

## Non-active surgical implants - Implants for osteosynthesis - Particular requirements

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	1
4	Intended performance .....	1
4.1	General .....	1
4.2	Intended purpose .....	2
4.3	Functional characteristics .....	2
4.4	Intended conditions of use .....	3
5	Design attributes .....	3
6	Materials .....	4
7	Design evaluation .....	4
7.1	General .....	4
7.2	Pre-clinical evaluation .....	4
7.3	Clinical evaluation .....	4
7.4	Post-market surveillance .....	4
8	Manufacturing .....	5
9	Sterilization .....	5
10	Packaging .....	5
11	Information supplied by manufacturer .....	5
11.1	General .....	5
11.2	Labelling .....	5
11.3	Instructions for use .....	5
11.4	Restrictions on combinations .....	5
11.5	Marking on implant .....	5
11.6	Marking for special purposes .....	5
Annex A (informative) Correspondence of the clauses of this International Standard to the fundamental principles outlined in ISO/TR 14283 .....		6
Annex B (informative) ISO standards referring to implants and associated instruments found acceptable through clinical use for given applications in osteosynthesis .....		7
Annex C (informative) ISO Standards referring to materials found acceptable through proven clinical use .....		10
Annex D (informative) Standards related to testing and design evaluation .....		12
Bibliography .....		13

