

# DIN EN ISO 10993-6:2007-08 (E)

## Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)

---

<b>Contents</b>		<b>Page</b>
Foreword .....		3
1	Scope .....	4
2	Normative references .....	4
3	Terms and definitions .....	5
4	Common provisions for implantation test methods .....	5
4.1	General .....	5
4.2	Preparation of specimens for implantation .....	5
5	Test methods, general aspects .....	6
5.1	Tissue and implantation site .....	6
5.2	Animals .....	6
5.3	Test periods .....	7
5.4	Surgery and testing conditions .....	8
5.5	Evaluation .....	9
6	Test report .....	11
Annex A (informative)	General considerations regarding implantation periods and tissue responses to degradable/resorbable materials .....	12
Annex B (normative)	Test methods for implantation in subcutaneous tissue .....	13
Annex C (normative)	Test method for implantation in muscle .....	15
Annex D (normative)	Test method for implantation in bone .....	17
Annex E (informative)	Examples of evaluation of local biological effects after implantation .....	20
Bibliography .....		22
Annex ZA (informative)	Clauses of this International Standard addressing essential requirements or other provisions of EU Directives 90/385/EEC for Active Implantable Medical Devices and 93/42/EEC for Medical Devices .....	25