

# DIN EN ISO 10993-4:2007-06 (E)

**Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (IS O 10993-4:2002+Amd.1:2006) (includes Amendment A1:2006)**

---

Contents	Page
Foreword to EN 10993-4:2002 .....	3
Introduction .....	5
1    Scope .....	5
2    Normative references .....	5
3    Terms and definitions .....	6
4    Abbreviated terms .....	7
5    Types of device in contact with blood (as categorized in ISO 10993-1) .....	8
5.1    Non-contact devices .....	8
5.2    External communicating devices .....	8
5.3    Implant devices .....	9
6    Characterization of blood interactions .....	9
6.1    General requirements .....	9
6.2    Categories of tests and blood interactions .....	14
6.3    Types of test .....	17
Annex A (informative) Preclinical evaluation of cardiovascular devices and prostheses .....	19
Annex B (informative) Laboratory tests -- Principles, scientific basis and interpretation .....	23
Annex C (informative) Evaluation of haemolytic properties of medical devices and their components .....	29
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directives 93/42/EEC and 90/385/EEC .....	36
Annex ZB (normative) Normative references to international publications with their relevant European publications .....	37
Bibliography .....	38