

DIN EN ISO 10993-4:2017-12 (E)

Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)

Contents		Page
European foreword		3
Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered		5
Annex ZB (informative) Relationship between this European Standard and the essential requirements of Directive 90/385/EEC [OJ L 189] aimed to be covered		7
Foreword		9
Introduction		11
1 Scope		12
2 Normative references		12
3 Terms and definitions		12
4 Abbreviated terms		15
5 Types of devices in contact with blood (as categorized in ISO 10993-1)		16
5.1 Non-blood-contact devices.....		16
5.2 External communicating devices.....		16
5.2.1 General.....		16
5.2.2 External communicating devices that serve as an indirect blood path.....		16
5.2.3 External communicating devices directly contacting circulating blood.....		16
5.3 Implant devices.....		17
6 Characterization of blood interactions		17
6.1 General requirements.....		17
6.2 Categories of tests and blood interactions.....		23
6.2.1 Recommended tests for interactions of devices with blood.....		23
6.2.2 Non-contact devices.....		24
6.2.3 External communicating devices and implant devices.....		24
6.2.4 Limitations.....		24
6.3 Types of tests.....		24
6.3.1 <i>In vitro</i> tests.....		24
6.3.2 <i>Ex vivo</i> tests.....		25
6.3.3 <i>In vivo</i> tests.....		25
Annex A (informative) Preclinical evaluation of cardiovascular devices and prostheses		27
Annex B (informative) Recommended laboratory tests — Principles, scientific basis and interpretation		28
Annex C (informative) Thrombosis — Methods for <i>in vivo</i> testing		43
Annex D (informative) Haematology/haemolysis — Methods for testing — Evaluation of haemolytic properties of medical devices and medical device materials		50
Annex E (informative) Complement — Methods for testing		55
Annex F (informative) Less common laboratory tests		60
Annex G (informative) Tests which are not recommended		64
Bibliography		66