

# 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)

---

<b>Contents</b>		Page
<b>European foreword</b> .....		3
<b>Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered</b> .....		5
<b>Annex ZB (informative) Relationship between this European Standard and the essential requirements of Directive 90/385/EEC [OJ L 189] aimed to be covered</b> .....		7
<b>Foreword</b> .....		9
<b>Introduction</b> .....		11
<b>1 Scope</b> .....		12
<b>2 Normative references</b> .....		12
<b>3 Terms and definitions</b> .....		12
<b>4 Abbreviated terms</b> .....		15
<b>5 Types of devices in contact with blood (as categorized in ISO 10993-1)</b> .....		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
<b>6 Characterization of blood interactions</b> .....		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
<b>Annex A (informative) Preclinical evaluation of cardiovascular devices and prostheses</b> .....		27
<b>Annex B (informative) Recommended laboratory tests — Principles, scientific basis and interpretation</b> .....		28
<b>Annex C (informative) Thrombosis — Methods for <i>in vivo</i> testing</b> .....		43
<b>Annex D (informative) Haematology/haemolysis — Methods for testing — Evaluation of haemolytic properties of medical devices and medical device materials</b> .....		50
<b>Annex E (informative) Complement — Methods for testing</b> .....		55
<b>Annex F (informative) Less common laboratory tests</b> .....		60
<b>Annex G (informative) Tests which are not recommended</b> .....		64
<b>Bibliography</b> .....		66