

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