

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