

# DIN EN ISO 10993-18:2021-03 (E)

## Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)

---

<b>Contents</b>	<b>Page</b>
<b>European foreword</b> .....	<b>4</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>6</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>8</b>
<b>Annex ZC (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered</b> .....	<b>10</b>
<b>Foreword</b> .....	<b>12</b>
<b>Introduction</b> .....	<b>13</b>
<b>1 Scope</b> .....	<b>14</b>
<b>2 Normative references</b> .....	<b>14</b>
<b>3 Terms and definitions</b> .....	<b>15</b>
<b>4 Symbols and abbreviated terms</b> .....	<b>19</b>
<b>5 Characterization procedure</b> .....	<b>20</b>
5.1 General.....	20
5.2 Establish medical device configuration and material composition.....	23
5.2.1 General.....	23
5.2.2 Information gathering.....	24
5.2.3 Information generation.....	24
5.3 Assess material/chemical equivalence to a clinically established material or medical device.....	25
5.4 Assess the hypothetical worst-case chemical release based on total exposure to the medical device's chemical constituents.....	26
5.4.1 Establish the hypothetical worst-case chemical release.....	26
5.4.2 Assess the hypothetical worst-case chemical release.....	26
5.5 Establish an analytical evaluation threshold.....	27
5.6 Estimate the chemical release; perform extraction study.....	27
5.7 Assess the estimated chemical release (extractables profile).....	30
5.8 Determine the actual chemical release; perform leachables study.....	30
5.9 Assess the actual chemical release (leachables profile).....	32
5.10 Exiting the chemical characterization process.....	32
<b>6 Chemical characterization parameters and methods</b> .....	<b>32</b>
6.1 General.....	32
6.2 Material composition.....	33
6.3 Extractables and leachables.....	35
6.4 Structural composition or configuration.....	37
6.5 Analytical methods.....	38
<b>7 Reporting of the chemical characterization data</b> .....	<b>39</b>

<b>Annex A (informative) General principles of chemical characterization</b> .....	<b>40</b>
<b>Annex B (informative) Information sources for chemical characterization</b> .....	<b>44</b>
<b>Annex C (informative) Principles for establishing biological equivalence</b> .....	<b>48</b>
<b>Annex D (informative) Principles of sample extraction</b> .....	<b>51</b>
<b>Annex E (informative) Calculation and application of the analytical evaluation threshold (AET)</b> ...	<b>63</b>
<b>Annex F (informative) Qualification of analytical methods used for extractables/leachables</b> .....	<b>71</b>
<b>Annex G (informative) Reporting details for analytical methods and chemical data</b> .....	<b>74</b>
<b>Bibliography</b> .....	<b>77</b>