

# DIN EN ISO 10993-13:2010-11 (E)

## Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)

---

<b>Contents</b>		<b>Page</b>
Foreword .....		3
Introduction .....		4
<b>1</b>	<b>Scope .....</b>	<b>5</b>
<b>2</b>	<b>Normative references .....</b>	<b>5</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>6</b>
<b>4</b>	<b>Degradation test methods .....</b>	<b>6</b>
<b>4.1</b>	<b>General procedures .....</b>	<b>6</b>
<b>4.2</b>	<b>Accelerated degradation test .....</b>	<b>9</b>
<b>4.3</b>	<b>Real-time degradation test in a simulated environment .....</b>	<b>10</b>
<b>5</b>	<b>Test procedures .....</b>	<b>10</b>
<b>5.1</b>	<b>General .....</b>	<b>10</b>
<b>5.2</b>	<b>Initial material characterization .....</b>	<b>10</b>
<b>5.3</b>	<b>Accelerated degradation test .....</b>	<b>10</b>
<b>5.4</b>	<b>Real-time degradation test in a simulated environment .....</b>	<b>13</b>
<b>6</b>	<b>Test report .....</b>	<b>14</b>
	<b>Annex A (informative) Analytical methods .....</b>	<b>15</b>
	<b>Annex B (informative) Environmental stress cracking (ESC) of polymers .....</b>	<b>16</b>
	<b>Bibliography .....</b>	<b>18</b>
	<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices .....</b>	<b>19</b>
	<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices .....</b>	<b>20</b>