

# DIN EN ISO 7198:2017-07 (E)

## Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches (I SO 7198:2016)

---

<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 EU Directive 93/42/EEC [OJ L 169] on medical devices</b> .....	<b>7</b>
<b>Foreword</b> .....	<b>10</b>
<b>Introduction</b> .....	<b>11</b>
<b>1 Scope</b> .....	<b>12</b>
<b>2 Normative references</b> .....	<b>13</b>
<b>3 Terms and definitions</b> .....	<b>13</b>
<b>4 General requirements</b> .....	<b>17</b>
4.1 Configuration designation for tubular vascular grafts.....	17
4.2 Size designation.....	18
4.2.1 Uniform straight tubular vascular grafts.....	18
4.2.2 Uniform bifurcated tubular vascular grafts.....	18
4.2.3 Tapered tubular vascular grafts.....	18
4.2.4 Other configurations of tubular vascular grafts.....	18
4.2.5 Vascular patches.....	18
4.3 Materials.....	18
4.3.1 General.....	18
4.3.2 Classification of tubular vascular grafts and vascular patches.....	18
4.3.3 Nomenclature.....	19
4.4 Intended clinical use designation.....	19
<b>5 Intended performance</b> .....	<b>20</b>
<b>6 Design attributes</b> .....	<b>20</b>
6.1 General.....	20
6.2 Tubular vascular grafts.....	20
6.3 Vascular patches.....	20
6.4 Coatings.....	21
6.5 Drug coatings and drug-eluting coatings.....	21
<b>7 Materials</b> .....	<b>21</b>
<b>8 Design evaluation</b> .....	<b>21</b>
8.1 General.....	21
8.2 Sampling.....	22
8.3 Conditioning of test samples.....	22
8.4 Reporting.....	22
8.5 Biocompatibility.....	23
8.5.1 Residual chemicals.....	23
8.5.2 Biocompatibility.....	23
8.6 Biostability.....	23
8.7 Bench and analytical tests.....	24
8.7.1 General.....	24
8.7.2 Tubular vascular grafts.....	24
8.7.3 Vascular patches.....	26

<b>9</b>	<b>Preclinical <i>in vivo</i> evaluation test methods for vascular prostheses</b>	<b>27</b>
9.1	Preclinical <i>in vivo</i> evaluation	27
9.1.1	Purpose	27
9.1.2	Specific aims	28
9.1.3	Protocol considerations	28
9.1.4	Data acquisition	28
9.1.5	Test report and additional information	29
<b>10</b>	<b>Clinical investigation methods for vascular prostheses</b>	<b>30</b>
10.1	Clinical investigation	30
10.1.1	Purpose	30
10.1.2	Specific aims	30
10.1.3	Protocol considerations	30
10.1.4	Data acquisition	31
10.1.5	Final report	34
10.2	Post market surveillance	35
<b>11</b>	<b>Manufacturing</b>	<b>35</b>
<b>12</b>	<b>Sterility</b>	<b>35</b>
<b>13</b>	<b>Packaging and labelling</b>	<b>36</b>
13.1	General	36
13.2	Unit container	36
13.3	Outer container	36
13.4	Shipping container	36
13.5	Maintenance of sterility in transit	36
13.6	Marking	36
13.6.1	Container label	36
13.6.2	Record label	37
13.6.3	General information and instructions for use	37
<b>Annex A (informative)</b>	<b>Test methods</b>	<b>38</b>
<b>Bibliography</b>		<b>65</b>