

DIN EN ISO 7198:2017-07 (E)

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

Contents	Page
European foreword	4
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] on medical devices	7
Foreword	10
Introduction	11
1 Scope	12
2 Normative references	13
3 Terms and definitions	13
4 General requirements	17
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
5 Intended performance	20
6 Design attributes	20
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
7 Materials	21
8 Design evaluation	21
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

9	Preclinical <i>in vivo</i> evaluation test methods for vascular prostheses	27
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
10	Clinical investigation methods for vascular prostheses	30
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
11	Manufacturing	35
12	Sterility	35
13	Packaging and labelling	36
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
Annex A (informative)	Test methods	38
Bibliography		65