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 *in vivo* evaluation test methods for vascular prostheses 27
9.1 Preclinical ***in vivo*** 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