

DIN EN ISO 25539-1:2018-05 (E)

Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2017)

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] aimed to be covered		6
Foreword		12
Introduction		13
1	Scope	15
2	Normative references	16
3	Terms and definitions	16
4	General requirements for endovascular system	18
4.1	Type of endovascular prosthesis.....	18
4.2	Materials and construction for endovascular system.....	18
4.3	Configuration and size designation for endovascular prosthesis.....	19
4.4	Intended clinical use for endovascular system.....	19
4.5	Balloon designation.....	20
5	Intended performance	20
6	Design attributes	20
6.1	General.....	20
6.2	Endovascular system.....	20
6.3	Endovascular prosthesis.....	20
6.4	Endovascular system and endovascular prosthesis.....	21
7	Materials	21
8	Design evaluation	21
8.1	General.....	21
8.2	Sampling.....	22
8.3	Conditioning of test samples.....	23
8.4	Reporting.....	23
8.5	Bench and analytical tests.....	24
8.5.1	Endovascular system and delivery system.....	24
8.5.2	Endovascular prosthesis.....	26
8.6	Preclinical <i>in vivo</i> evaluation.....	32
8.6.1	Purpose.....	32
8.6.2	Specific aims.....	32
8.6.3	Protocol considerations.....	33
8.6.4	Data acquisition.....	33
8.6.5	Test report and additional information.....	35
8.7	Clinical evaluation.....	35
8.7.1	Purpose.....	35
8.7.2	Specific aims.....	36
8.7.3	Protocol considerations.....	36
8.7.4	Data acquisition.....	37
8.7.5	Final report.....	40

9	Post-market surveillance	41
10	Manufacturing	41
11	Sterilization	41
	11.1 Products supplied sterile.....	41
	11.2 Sterilization residuals.....	41
12	Packaging	42
	12.1 Protection from damage in storage and transport.....	42
	12.1.1 General.....	42
	12.1.2 Unit container.....	42
	12.1.3 Outer container.....	42
	12.1.4 Shipping container.....	42
	12.1.5 Maintenance of sterility in transit.....	42
	12.2 Labelling.....	42
	12.2.1 Container label.....	42
	12.2.2 Record label.....	43
	12.3 Instructions for use.....	43
	12.3.1 General.....	43
	12.3.2 Information and instructions for use for endovascular systems.....	43
	Annex A (informative) Relationship between testing requirements and device attributes and potential failure modes	45
	Annex B (informative) Description of clinical and device effects of failure	59
	Annex C (informative) Bench and analytical tests	63
	Annex D (informative) Test methods	71
	Bibliography	135