

ISO 25539-2:2012-12 (E)

Cardiovascular implants - Endovascular devices - Part 2: Vascular stents

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General requirements	4
4.1	Classification	4
4.2	Size	4
4.3	Intended clinical use designation	5
5	Intended performance	5
6	Design attributes	5
6.1	General	5
6.2	Delivery system and stent system	6
6.3	Implant	6
7	Materials	7
8	Design evaluation	7
8.1	General	7
8.2	Sampling	8
8.3	Conditioning of test samples	8
8.4	Reporting	8
8.5	Delivery system and stent system	9
8.6	Stent	15
8.7	Preclinical in vivo evaluation	23
8.8	Clinical evaluation	27
9	Post-market surveillance	30
10	Manufacturing	30
11	Sterilization	30
11.1	Products supplied sterile	30
11.2	Products supplied non-sterile	31
11.3	Sterilization residuals	31
12	Packaging	31
12.1	Protection from damage in storage and transport	31
12.2	Marking	31
12.3	Information supplied by the manufacturer	32
Annex A (informative)	Attributes of endovascular devices -- Vascular stents -- Technical and clinical consideration	34
Annex B (informative)	Bench and analytical tests	41

Annex C (informative) Definitions of reportable clinical events	45
Annex D (informative) Test methods	48
Annex E (informative) Supplement to fatigue durability test analytical approach	85
Bibliography	88