

# ISO 25539-1:2003-03 (E)

## Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	2
4	Intended performance .....	3
5	Design attributes .....	3
5.1	General .....	3
5.2	Delivery system .....	4
5.3	Implant .....	4
6	Materials .....	4
7	Design evaluation .....	5
7.1	General .....	5
7.2	Delivery (and/or endovascular) system .....	5
7.3	Implant .....	11
7.4	Preclinical in vivo evaluation .....	19
7.5	Clinical evaluation .....	22
8	Manufacturing .....	25
9	Sterilization .....	25
9.1	Products supplied sterile .....	25
9.2	Products supplied non-sterile .....	26
9.3	Sterilization residuals .....	26
10	Packaging .....	26
10.1	Protection from damage in storage and transport .....	26
10.2	Marking .....	27
10.3	Information supplied by the manufacturer .....	27
Annex A (informative) Attributes of endovascular devices-- Technical and clinical considerations ..		29
Annex B (informative) Bench and analytical tests .....		36
Annex C (informative) Definitions of reportable clinical events .....		39
Bibliography .....		42