

# DIN EN ISO 25539-3:2012-03 (E)

## Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters (ISO 25539-3:2011)

---

<b>Contents</b>		<b>Page</b>
Foreword .....		3
Introduction .....		4
1	Scope .....	5
2	Normative references .....	5
3	Terms and definitions .....	6
4	General requirements .....	9
4.1	Classification .....	9
4.2	Size .....	9
5	Intended performance .....	9
6	Design attributes .....	9
6.1	General .....	9
6.2	Sheath/dilator kit for endovascular filter system .....	9
6.3	Filter system .....	9
6.4	Filter .....	9
6.5	Optional filter .....	10
6.6	Sheath/dilator kit for endovascular retrieval/conversion system .....	10
6.7	Retrieval/conversion system .....	10
6.8	Endovascular systems .....	10
7	Materials .....	11
8	Design evaluation .....	11
8.1	General .....	11
8.2	Sampling .....	11
8.3	Conditioning of test samples .....	12
8.4	Reporting .....	12
8.5	Bench and analytical tests .....	13
8.6	Preclinical in vivo evaluation .....	28
8.7	Clinical evaluation .....	32
9	Post-market surveillance .....	36
10	Manufacturing .....	36
11	Sterilization .....	36
11.1	Products supplied sterile .....	36
11.2	Products supplied non-sterile .....	37
11.3	Sterilization residuals .....	37
12	Packaging .....	37
12.1	Protection from damage in storage and transport .....	37
12.2	Marking .....	38
12.3	Information supplied by the manufacturer .....	39

<b>Annex A (informative) Attributes of endovascular devices -- Vena cava filters -- Technical and clinical considerations .....</b>	<b>41</b>
<b>Annex B (informative) Descriptions of potential device effects of failure and failure modes and descriptions of detrimental clinical effects .....</b>	<b>55</b>
<b>Annex C (informative) Bench and analytical tests .....</b>	<b>59</b>
<b>Annex D (informative) Test methods .....</b>	<b>63</b>
<b>Annex E (informative) Examples of terms for clinical use of vena cava filters .....</b>	<b>90</b>
<b>Bibliography .....</b>	<b>92</b>
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC .....</b>	<b>98</b>