

ISO/TS 12417:2011-06 (E)

Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	2
3	Terms and definitions	2
4	General requirements	5
4.1	Classification	5
4.2	Intended clinical location	5
5	Intended performance	6
6	Design attributes	6
6.1	General	6
6.2	Drug-containing part of the VDDCP (DCP)	6
6.2.1	General	6
6.2.2	Matrix	7
6.2.3	Active pharmaceutical ingredient (API)	7
7	Materials	7
8	Design evaluation	8
8.1	General	8
8.2	Sampling	8
8.3	Conditioning of test samples	9
8.4	Reporting	9
8.5	Testing of the device part of the VDDCP	10
8.6	Testing of the drug-containing part of the VDDCP	10
8.7	Requirements for the drug-containing part of the VDDCP	10
8.7.1	Ability to access	10
8.7.2	Ability to deploy the VDDCP and deliver the API from the DCP	11
8.7.3	Ability to withdraw	13
8.7.4	Functionality	13
8.7.5	Compatibility with procedural fluids	14
8.7.6	Corrosion	15
8.7.7	Magnetic resonance imaging (MRI) safety and compatibility	15
8.7.8	Biocompatibility	15
8.8	Preclinical in vivo evaluation	16
8.8.1	Purpose	16
8.8.2	Specific aims	16
8.8.3	Protocol	16
8.8.4	Data acquisition	18
8.8.5	Test report and additional information	20
8.9	Clinical evaluation	20
8.9.1	Purpose	20
8.9.2	Specific aims	21
8.9.3	Clinical-investigation plan	21

8.9.4	Data acquisition	22
8.9.5	Final report	24
9	Post-market surveillance	25
10	Manufacturing	25
10.1	General	25
10.2	Raw-material analysis and reporting for the API	25
10.3	Raw-material analysis and reporting for excipients	26
10.4	VDDCP batch release testing	26
11	Sterilization	27
11.1	Products supplied sterile	27
11.1.1	Labelling	27
11.2	Products supplied non-sterile	27
11.3	Sterilization residuals	27
12	Packaging	27
12.1	Protection from damage during storage and transport	27
12.1.1	General	27
12.1.2	Unit container	27
12.1.3	Shipping container	27
12.1.4	Maintenance of sterility in transit	28
12.2	Marking	28
12.2.1	VDDCP label(s)	28
12.2.2	Record label	29
12.3	Information supplied by the manufacturer	29
12.3.1	General	29
12.3.2	Information and instructions for use (IFU)	29
	Annex A (informative) Definitions of potential clinical events	31
	Annex B (informative) Information on device- and drug-related aspects -- Applicable documents for local guidance	36
	Bibliography	43