

DIN EN ISO 12417-1:2024-08 (E)

Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements (ISO 12417-1:2024)

Contents		Page
European foreword		4
Foreword		5
Introduction		6
1	Scope	7
2	Normative references	8
3	Terms and definitions	8
4	Intended performance	12
4.1	General	12
4.2	Classification	12
4.3	Intended clinical location	13
5	Design attributes	13
5.1	General	13
5.2	Drug-containing part of the VDDCP	13
5.2.1	General	13
5.2.2	Matrix	14
5.2.3	Active pharmaceutical ingredient	14
6	Materials	15
7	Design evaluation	15
7.1	General	15
7.2	Pre-clinical evaluation	16
7.2.1	Sampling	16
7.2.2	Conditioning of test samples	16
7.2.3	Pre-clinical in vitro test reports and additional information	17
7.2.4	Pre-clinical in vitro evaluation	17
7.2.5	Preclinical in vivo evaluation	23
7.3	Clinical evaluation	28
7.3.1	Purpose	28
7.3.2	Specific aims	28
7.3.3	Clinical investigation plan	28
7.3.4	Data acquisition	29
7.3.5	Final report	31
7.4	Post-market surveillance	32
8	Manufacturing	32
8.1	General	32
8.2	Raw material reporting and analysis of the API	32
8.3	Raw material analysis and reporting for excipients	33
8.4	VDDCP batch release testing	33
9	Sterilization	34
9.1	Products supplied sterile — Testing to support “Sterile” labelling	34
9.2	Products supplied non-sterile	34
9.3	Sterilization residuals	34
10	Packaging	34
10.1	General	34
10.2	Considerations for VDDCPs	34
10.3	Impact of changes in storage and shipping temperatures on VDDCP	34

11	Information supplied by the manufacturer	35
11.1	General.....	35
11.2	Labelling.....	35
11.2.1	VDDCP label(s).....	35
11.2.2	Record label.....	35
11.3	Instructions for use.....	36
Annex A	(informative) Description of potential clinical and technical events	37
Annex B	(informative) Local information regarding submission issues for VDDCPs	42
Bibliography	48