

ISO 22679:2021-11 (E)

Cardiovascular implants - Transcatheter cardiac occluders

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Abbreviations	6
5	Fundamental requirements	7
5.1	General	7
5.2	Risk management	7
6	Device description	8
6.1	General	8
6.2	Intended use	8
6.3	Design inputs	8
6.3.1	Operational principles and specifications	8
6.3.2	Functional, performance and safety requirements	8
6.3.3	Implant procedure: Device and usability requirements	9
6.3.4	Packaging, labelling and sterilization	10
6.4	Design outputs	10
6.5	Design transfer (manufacturing verification or validation)	10
7	Design verification and validation	10
7.1	General requirements	10
7.2	In vitro assessment	11
7.2.1	General	11
7.2.2	Test conditions, sample selection and reporting requirements	11
7.2.3	Material property assessment	12
7.2.4	Structural performance assessment	13
7.2.5	Component corrosion assessment	14
7.2.6	Visibility	14
7.2.7	Visual inspection	15
7.2.8	Dimensional verification	15
7.2.9	Device MRI compatibility	15
7.2.10	Simulated use assessment	15
7.2.11	Usability engineering process	15
7.2.12	Design- or procedure-specific testing	15
7.3	Preclinical in vivo evaluation	15
7.3.1	General	15
7.3.2	Overall requirements	15
7.3.3	Methods	17
7.3.4	Test report	18
7.4	Clinical investigations	19
7.4.1	General	19
7.4.2	Study considerations	20
7.4.3	Imaging assessment	21
7.4.4	Study design	21

7.4.5	Explant analysis	21
7.4.6	Pilot study considerations	22
7.4.7	Study endpoints	22
7.4.8	Ethical considerations	22
7.4.9	Pivotal studies: Distribution of subjects and investigators	23
7.4.10	Site qualification and training requirements	23
7.4.11	Study population	23
7.4.12	Statistical considerations	24
7.4.13	Sample size	25
7.4.14	Duration of study	25
7.4.15	Patient selection criteria	25
7.4.16	Clinical data requirements	26
Annex A (informative) Rationale for the provisions of this document		31
Annex B (informative) Transcatheter cardiac occluder hazard analysis example		34
Annex C (normative) Packaging		36
Annex D (normative) Product labels and instructions for use		37
Annex E (normative) Sterilization		38
Annex F (informative) Corrosion assessment		39
Annex G (informative) In vitro test guidelines for paediatric devices		42
Annex H (informative) Fatigue and durability assessment		44
Annex I (normative) Adverse event classification during clinical investigation		50
Annex J (informative) Imaging protocol		55
Annex K (informative) Clinical investigation endpoints for transcatheter cardiac occluders: Suggestions for endpoints and their timing		56
Annex L (informative) Examples of design specific testing		59
Annex M (informative) Guidelines for delivery system design evaluation		61
Annex N (normative) Preclinical in vivo evaluation		63
Annex O (informative) In vitro test pressure guidelines		66
Annex P (informative) Training for physicians and support staff		68
Bibliography		69