

DIN EN ISO 5840-2:2016-05 (E)

Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes (ISO 5840-2:2015)

Contents		Page
European foreword		4
Foreword		5
Introduction		6
1	Scope	7
2	Normative references	7
3	Terms and definitions	8
4	Abbreviations	10
5	Fundamental requirements	10
6	Device description	11
6.1	Intended use	11
6.2	Design inputs	11
6.2.1	Operational specifications	11
6.2.2	Performance specifications	11
6.2.3	Packaging, labelling, and sterilization	12
6.3	Design outputs	12
6.3.1	General	12
6.4	Design transfer (manufacturing qualification)	12
6.5	Risk management	12
7	Design verification testing and analysis/design validation	12
7.1	General requirements	12
7.2	<i>In vitro</i> assessment	13
7.2.1	Test conditions, sample selection, and reporting requirements	13
7.2.2	Material property assessment	14
7.2.3	Hydrodynamic performance assessment	14
7.2.4	Structural performance assessment	16
7.2.5	Device MRI safety	17
7.2.6	Additional implant design evaluation requirements	17
7.2.7	Design specific testing	18
7.2.8	Simulated use	18
7.2.9	Human factors/usability assessment	18
7.3	Preclinical <i>in vivo</i> evaluation	18
7.3.1	Overall requirements	18
7.3.2	Methods	19
7.3.3	Test report	20
7.4	Clinical investigation	21
7.4.1	General	21
7.4.2	Statistical considerations	21
7.4.3	Distribution of subjects and investigators	21
7.4.4	Sample size	21
7.4.5	Entry criteria	22
7.4.6	Duration of the study	22
7.4.7	Clinical data requirements	22
7.4.8	Clinical investigation report	24

Annex A (informative) Heart valve substitute hazards, associated failure modes, and evaluation methods	26
Annex B (informative) <i>In vitro</i> procedures for testing unstented or similar valves in compliant chambers	29
Annex C (informative) Preclinical <i>in vivo</i> evaluation	31
Annex D (informative) Description of the surgical heart valve substitute	34
Annex E (informative) Examples of components of some surgical heart valve substitutes	36
Annex F (informative) Guidelines for verification of hydrodynamic performance	40
Annex G (informative) Durability testing	49
Annex H (informative) Examples of design specific testing	51
Annex I (informative) Fatigue assessment	53
Annex J (normative) Methods of evaluating clinical data	59
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices	60
Bibliography	61