

DIN EN ISO 5840-1:2025-10 (E)

Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements (ISO 5840-1:2021 + Amd 1:2025) (includes Amendment A1:2025)

Contents		Page
Foreword		v
A1 Foreword to Amendment A1 A1		vi
Introduction		vii
1 Scope		1
2 Normative references		1
3 Terms and definitions		2
4 Abbreviations		15
5 Fundamental requirements		15
6 Device description		16
6.1 General		16
6.2 Intended use		16
6.3 Design inputs		16
6.3.1 Operational specifications		16
6.3.2 Performance specifications		17
6.3.3 Implant procedure		17
6.3.4 Packaging, labelling, and sterilization		17
6.4 Design outputs		18
6.5 Design transfer (manufacturing verification/validation)		18
6.6 Risk management		18
7 Design verification and validation		18
7.1 General requirements		18
7.2 In vitro assessment		18
7.2.1 General		18
7.2.2 Test conditions, sample selection and reporting requirements		19
7.2.3 Material property assessment		20
7.2.4 Hydrodynamic performance assessment		21
7.2.5 Structural performance assessment		21
7.2.6 Design- or procedure-specific testing		23
7.2.7 Device MRI compatibility		23
7.2.8 Simulated use		23
7.2.9 Human factors/usability assessment		23
7.2.10 Implant thrombogenic and haemolytic potential assessment		23
7.3 Preclinical in vivo evaluation		24
7.4 Clinical investigations		24
Annex A (informative) Rationale for the provisions of ISO 5840-1		25
Annex B (normative) Packaging		28
Annex C (normative) Product labels, instructions for use, and training		29
Annex D (normative) Sterilization		32

Annex E (normative) In vitro test guidelines for paediatric devices	33
Annex F (informative) Corrosion assessment	37
Annex G (informative) Echocardiographic protocol	40
Annex H (informative) Assessment of implant thrombogenic and haemolytic potential	42
Annex I (informative) Guidelines for hydrodynamic performance characterization by steady flow testing	53
Annex J (normative) Durability testing	60
Annex K (informative) Fatigue assessment	68
Annex L (normative) Clinical investigation endpoints for heart valve replacement devices	73
Bibliography	76