ISO 5840-1:2021 (E)

Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements

Contents

1

2

3

4

5

6

7

| | | Foreword |
|------------------------------------|------|--|
| | | Introduction |
| | | Scope |
| | | Normative references |
| | | Terms and definitions |
| | | Abbreviations |
| | | Fundamental requirements |
| | | Device description |
| | 6.1 | General |
| | 6.2 | Intended use |
| | 6.3 | Design inputs |
| | 6.3. | 1 Operational specifications |
| | 6.3. | 2 Performance specifications |
| | 6.3. | 3 Implant procedure |
| | 6.3. | 4 Packaging, labelling, and sterilization |
| | 6.4 | Design outputs |
| | 6.5 | Design transfer (manufacturing verification/validation) |
| | 6.6 | Risk management |
| Design verification and validation | | Design verification and validation |
| | 7.1 | General requirements |
| | 7.2 | In vitro assessment |
| | 7.2. | 1 General |
| | 7.2. | 2 Test conditions, sample selection and reporting requirements |
| | 7.2. | 2.1 Test articles and sample selection |
| | 7.2. | 2.2 Test conditions |
| | 7.2. | 2.3 Reporting requirements |
| | 7.2. | 3 Material property assessment |
| | 7.2. | 3.1 General |
| | 7.2. | 3.2 Biological safety |
| | 7.2. | 3.3 Material and mechanical property testing |
| | 7.2. | 4 Hydrodynamic performance assessment |
| | 7.2. | 5 Structural performance assessment |
| | 7.2. | 5.1 General |
| | 7.2. | 5.2 Implant durability assessment |
| | 7.2. | 5.3 Device structural component fatigue assessment |
| | 7.2. | 5.4 Component corrosion assessment |
| | 7.2. | 6 Design- or procedure-specific testing |
| | 7.2. | 7 Device MRI compatibility |

- 7.2.7 Device MRI cor 7.2.8 Simulated use
- 7.2.9 Human factors/usability assessment
- 7.2.10 Implant thrombogenic and haemolytic potential assessment
- 7.3 Preclinical in vivo evaluation
- 7.4 Clinical investigations

Annex A (informative) Rationale for the provisions of ISO 5840-1

- A.1 Rationale for a risk-based approach
- Rationale for preclinical in vivo evaluation A.2
- A.3 Rationale for design verification and design validation testing
- A.4 Rationale for echocardiographic assessment
- Rationale for clinical evaluation reporting A.5
- A.6 Rationale for device sizing within labelling and instructions for use
- A.7 Rationale for human factors engineering

Annex B (normative) Packaging

- **B.1** Requirements
- Principle **B.2**
- **B.3** Containers
- B.3.1 Unit container(s)
- B.3.2 **Outer container**

Annex C (normative) Product labels, instructions for use, and training

- C.1 General
- C.1.1 **General requirements**
- C.1.2 Unit-container label
- C.1.3 **Outer-container label**
- C.1.4 Instructions for use
- C.1.5 Labels for medical records
- C.2 Training for physicians and support staff
- (normative) Sterilization Annex D

Annex E (normative) In vitro test guidelines for paediatric devices

- E.1 General and paediatric definitions
- Pulsatile flow test conditions Left side Pulsatile flow test conditions Right side E.2
- E.3
- E.4 Steady back pressure and forward flow conditions - Left side
- E.5 Steady back pressure and forward flow conditions - Right side
- Accelerated wear testing (AWT) test conditions Left side E.6
- Accelerated wear testing (AWT) test conditions Right side E.7
- E.8 FEA/life analysis conditions — Left side
- FEA/life analysis conditions Right side E.9

Annex F (informative) Corrosion assessment

- F.1 Rationale
- F.2 General
- **F.3 Pitting corrosion**
- Crevice corrosion F 4
- F.5 Galvanic corrosion
- F.6 **Corrosion fatigue**
- F.7 Fretting (wear) and fretting corrosion
- **F.8** Post-fatigue corrosion evaluation

Annex G (informative) Echocardiographic protocol

- G.1 General
- Echocardiographic studies G.2
- G.3 Data collected

Annex H (informative) Assessment of implant thrombogenic and haemolytic potential

- Rationale H.1
- H.2 General
- Experimental flow field assessment H.3
- H.3.1 General
- H.3.2 Test apparatus requirements
- H.3.3 Test procedure
- Test report H.3.4
- Computational flow field assessment H.4
- H.4.1 General
- H.4.2 **Computational Model**
- H.4.3 Error analysis and estimation

- H.4.4 Computational simulations
- H.4.5 Study report
- H.5 Ex vivo blood testing
- H.5.1 General
- H.5.2 Test apparatus requirements
- H.5.3 Test procedure
- H.5.4 Test report
- Annex I (informative) Guidelines for hydrodynamic performance characterization by steady flow testing
 - I.1 General
 - I.2 Steady forward flow testing
 - I.2.1 Measuring equipment accuracy
 - I.2.2 Test apparatus requirements
 - I.2.3 Test procedure
 - I.2.4 Test report
 - I.3 Steady back flow leakage testing
 - I.3.1 Measuring equipment accuracy
 - I.3.2 Test apparatus requirements
 - I.3.3 Test procedure
 - I.3.4 Test report

Annex J (normative) Durability testing

- J.1 Rationale
- J.2 General
- J.3 Accelerated wear testing
- J.3.1 General
- J.3.2 Sample requirements
- J.3.3 Test apparatus requirements
- J.3.4 Test procedure
- J.3.5 Test report
- J.4 Dynamic failure mode testing
- J.4.1 General
- J.4.2 Sample requirements
- J.4.3 Test apparatus requirements
- J.4.4 Test procedure
- J.4.5 Test report
- J.5 Real-time wear testing
- J.5.1 General
- J.5.2 Test apparatus requirements
- J.5.3 Test apparatus requirements
- J.5.4 Test procedure
- J.5.5 Test report
- Annex K (informative) Fatigue assessment
 - K.1 General
 - K.2 Determination of in vivo boundary conditions
 - K.3 Structural component stress/strain analysis
 - K.4 Material fatigue strength determination
 - K.5 Fatigue safety factor or probability of fatigue fracture determination
 - K.6 Component fatigue demonstration test
- Annex L (normative) Clinical investigation endpoints for heart valve replacement devices
 - L.1 General
 - L.2 Single endpoints
 - L.2.1 General
 - L.2.2 Safety
 - L.2.3 Effectiveness
 - L.3 Heart failure hospitalization definition
 - L.4 Composite endpoints
 - L.5 Timing of endpoints