

# ISO 5840-1:2015-09 (E)

## Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	2
4	Abbreviations .....	11
5	Fundamental requirements .....	12
6	Device description .....	12
6.1	Intended use .....	12
6.2	Design inputs .....	12
6.2.1	Operational specifications .....	12
6.2.2	Performance specifications .....	12
6.2.3	Implant procedure .....	12
6.2.4	Packaging, labelling, and sterilization .....	13
6.3	Design outputs .....	13
6.4	Design transfer (manufacturing verification/validation) .....	14
6.5	Risk management .....	14
7	Design verification, testing and analysis/design validation .....	15
7.1	General requirements .....	15
7.2	In vitro assessment .....	15
7.3	Preclinical in vivo evaluation .....	15
7.4	Clinical investigations .....	15
Annex A (informative)	Rationale for the provisions of this part of ISO 5480 .....	16
Annex B (normative)	Packaging .....	19
Annex C (normative)	Product labels, instructions for use, and training .....	20
Annex D (normative)	Sterilization .....	23
Annex E (informative)	In vitro test guidelines for paediatric devices .....	24
Annex F (informative)	Statistical procedures when using in vitro performance criteria .....	28
Annex G (informative)	Examples and definitions of some physical and material properties of heart valve systems .....	29
Annex H (informative)	Examples of standards applicable to testing of materials and components of heart valve systems .....	40
Annex I (informative)	Raw and post-conditioning mechanical properties for support structure materials .....	46

<b>Annex J (informative) Corrosion assessment .....</b>	<b>48</b>
<b>Annex K (informative) Echocardiographic protocol .....</b>	<b>51</b>
<b>Bibliography .....</b>	<b>54</b>