

# ISO 5910:2024-07 (E)

## Cardiovascular implants and extracorporeal systems - Cardiac valve repair devices

### Contents

Page

- Foreword..... v
- 1 Scope..... 1
- 2 Normative references..... 1
- 3 Terms and definitions..... 2
- 4 Abbreviated terms..... 9
- 5 Fundamental requirements..... 10
  - 5.1 General..... 10
  - 5.2 Risk management..... 10
- 6 Device design..... 10
  - 6.1 Intended use and indication for use..... 10
  - 6.2 Design inputs..... 10
    - 6.2.1 General..... 10
    - 6.2.2 Operational specifications..... 10
    - 6.2.3 Functional, performance and safety requirements..... 12
    - 6.2.4 Usability..... 13
    - 6.2.5 Packaging, labelling and sterilization..... 13
  - 6.3 Design outputs..... 13
  - 6.4 Design transfer (manufacturing verification and validation)..... 13
- 7 Design verification testing and analysis, and design validation..... 14
  - 7.1 General requirements..... 14
  - 7.2 In vitro assessment..... 14
    - 7.2.1 General..... 14
    - 7.2.2 Test articles, sample selection, test conditions and reporting requirements..... 14
    - 7.2.3 Device material property assessment..... 16
    - 7.2.4 Device durability assessment..... 17
    - 7.2.5 Device corrosion assessment..... 17
    - 7.2.6 Design specific testing..... 17
    - 7.2.7 Visibility..... 17
    - 7.2.8 Simulated use assessment..... 18
    - 7.2.9 Human factors and usability assessment..... 18
    - 7.2.10 Device MRI safety..... 18
  - 7.3 Preclinical in vivo evaluation..... 18
    - 7.3.1 General..... 18
    - 7.3.2 Overall requirements..... 18
    - 7.3.3 Methods..... 20
    - 7.3.4 Test report..... 21
  - 7.4 Clinical investigations..... 22
    - 7.4.1 General..... 22
    - 7.4.2 Study considerations..... 22
    - 7.4.3 Study end points..... 24
    - 7.4.4 Ethical considerations..... 25
    - 7.4.5 Distribution of subjects and investigators..... 25
    - 7.4.6 Statistical considerations including sample size and duration..... 26
    - 7.4.7 Patient selection criteria..... 27
    - 7.4.8 Clinical data requirements..... 28
    - 7.4.9 Clinical investigation analysis and reporting..... 31
    - 7.4.10 Post-market clinical follow-up..... 31

<b>8</b>	<b>Manufacturing verification and validation</b>	<b>32</b>
<b>Annex A</b> (informative)	<b>Rationale for the provisions of this document</b>	<b>33</b>
<b>Annex B</b> (informative)	<b>Types and examples of heart valve repair devices and delivery systems</b>	<b>36</b>
<b>Annex C</b> (normative)	<b>Packaging</b>	<b>43</b>
<b>Annex D</b> (normative)	<b>Product labels, instructions for use and training</b>	<b>44</b>
<b>Annex E</b> (normative)	<b>Sterilization</b>	<b>47</b>
<b>Annex F</b> (informative)	<b>Heart valve repair system characteristics</b>	<b>48</b>
<b>Annex G</b> (informative)	<b>Example of a transcatheter heart valve repair system hazard analysis</b>	<b>50</b>
<b>Annex H</b> (informative)	<b>In vitro test guidelines for paediatric devices</b>	<b>51</b>
<b>Annex I</b> (informative)	<b>Identification of boundary conditions</b>	<b>54</b>
<b>Annex J</b> (informative)	<b>Test platforms for in vitro testing</b>	<b>58</b>
<b>Annex K</b> (informative)	<b>Considerations for device material properties undergoing alterations post implantation</b>	<b>60</b>
<b>Annex L</b> (informative)	<b>Corrosion assessment</b>	<b>61</b>
<b>Annex M</b> (informative)	<b>Durability assessment</b>	<b>64</b>
<b>Annex N</b> (informative)	<b>Additional device design evaluation considerations</b>	<b>71</b>
<b>Annex O</b> (normative)	<b>Delivery system design evaluation</b>	<b>74</b>
<b>Annex P</b> (informative)	<b>Preclinical ex vivo and in vivo evaluations</b>	<b>76</b>
<b>Annex Q</b> (normative)	<b>Adverse event classification during clinical investigation</b>	<b>80</b>
<b>Annex R</b> (informative)	<b>Multimodality imaging of TAVr, TMVr and TTVr (pre-, peri- and post-implantation)</b>	<b>86</b>
<b>Annex S</b> (informative)	<b>Clinical investigation end points for valve repair devices: Suggestions for end points and their timing</b>	<b>91</b>
	<b>Bibliography</b>	<b>95</b>