

# 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>