ISO 18242:2016-09 (E)

Cardiovascular implants and extracorporeal systems - Centrifugal blood pumps

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Requirements 3
4.1 Biological characteristics 3
4.1.1 Sterility and non-pyrogenicity 3
4.1.2 Biocompatibility 3
4.2 Physical characteristics 3
4.2.1 Blood pathway integrity 3
4.2.2 Prime volume 3
4.2.3 Connector integrity 3
4.3 Performance characteristics 3
4.3.1 Hydraulic performance 3
4.3.2 Blood cell damage 3
4.3.3 Bearing durability 4
4.3.4 Shelf life 4

5 Tests and measurements to determine compliance with this document 4
5.1 General 4
5.1.1 Tests and measurements 4
5.1.2 Operating variables 4
5.1.3 Temperature 4
5.1.4 Relationship between variables 4
5.1.5 Procedures 5
5.1.6 Driver/console 5
5.2 Biological characteristics 5
5.2.1 Sterility and non-pyrogenicity 5
5.2.2 Biocompatibility 5
5.3 Physical characteristics 5
5.3.1 Blood pathway integrity 5
5.3.2 Prime volume 5
5.3.3 Connectors 5
5.4 Performance characteristics 6
5.4.1 Hydraulic performance 6
5.4.2 Blood cell damage 6
5.4.3 Bearing wear 7
5.4.4 Shelf life 7

6 Information supplied by the manufacturer 7
6.1 Information on the device 7
6.2 Information on the packaging 8
6.2.1 Unit container 8
6.2.2 Shipping container 8
6.3 Information in the accompanying documents 8
6.4 Information in the accompanying documents in a prominent form 9

7 Packaging 9

Bibliography 10