ISO 18241:2016-08 (E)

Cardiovascular implants and extracorporeal systems - Cardiopulmonary bypass systems - Venous bubble traps

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 Connectors 3
4.3 Performance characteristics 3
4.3.1 Blood cell damage 3
4.3.2 Air removal efficiency 3
4.3.3 Flow rate capacity 3
4.3.4 Shelf life 4

5 Tests and measurements to determine compliance with this document 4
5.1 General 4
5.2 Biological characteristics 4
5.2.1 Sterility and non-pyrogenicity 4
5.2.2 Biocompatibility 4
5.3 Physical characteristics 4
5.3.1 Blood pathway integrity 4
5.3.2 Prime volume 4
5.3.3 Connectors 4
5.4 Performance characteristics 5
5.4.1 Blood cell damage 5
5.4.2 Air removal efficiency 6
5.4.3 Flow rate and pressure drop 6
5.4.4 Shelf life 7

6 Information supplied by the manufacturer 7
6.1 Information on the venous bubble trap 7
6.2 Information on the packaging 7
6.2.1 Information on the unit container 7
6.2.2 Information on the shipping container 7
6.3 Information in the accompanying documents 8
6.4 Information in the accompanying documents in a prominent form 8

7 Packaging 8

Bibliography 9