ISO 7199:2016-11 (E)

Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

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 4
4.2.1 Blood pathway integrity 4
4.2.2 Heat exchanger fluid pathway integrity 4
4.2.3 Blood volumes 4
4.2.4 Connectors 4
4.3 Performance characteristics 4
4.3.1 Oxygen and carbon dioxide transfer rates 4
4.3.2 Heat exchanger performance factor 4
4.3.3 Integral arterial filtration efficiency 4
4.3.4 Integral arterial filter flow rate capacity 4
4.3.5 Integral arterial filter air handling capability 4
4.3.6 Blood cell damage 5
4.3.7 Time-dependent performance changes 5
4.3.8 Shelf life 5

5 Tests and measurements to determine compliance with this document 5
5.1 General 5
5.2 Biological characteristics 5
5.2.1 Sterility and non-pyrogenicity 5
5.2.2 Biocompatibility 5
5.3 Physical characteristics 6
5.3.1 Blood pathway integrity 6
5.3.2 Heat exchanger water pathway integrity 6
5.3.3 Blood volumes 6
5.3.4 Connectors 6
5.4 Performance characteristics 7
5.4.1 Oxygen and carbon dioxide transfer rates 7
5.4.2 Heat exchanger performance factor 8
5.4.3 Blood cell damage 8
5.4.4 Shelf life 8
5.4.5 Filtration efficiency 9
5.4.6 Integral arterial filter flow rate 9
5.4.7 Air-handling capability of integral arterial filter 9

6 Information supplied by the manufacturer 10
6.1 Information on the oxygenator 10
6.2 Information on the packaging 11
6.2.1 Unit container 11

6.2.2 Shipping container 11
6.3 Information in the accompanying documents 11
6.4 Information in the accompanying documents in a prominent form 12

7 Packaging 12

Bibliography 13