ISO 7199:2009-04 (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
4.2 Physical characteristics 3
4.3 Performance characteristics 3

5 Tests and measurements to determine compliance with this International Standard 4
5.1 General 4
5.2 Biological characteristics 4
5.3 Physical characteristics 5
5.4 Performance characteristics 5

6 Information supplied by the manufacturer 8
6.1 Information to be given on the oxygenator 8
6.2 Information to be given on the packaging 8
6.3 Information to be given in the accompanying documents 9
6.4 Information to be given in the accompanying documents in a prominent form 10

7 Packaging 10

Bibliography 11