ISO 10555-4:2013-06 (E)

Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters

Contents

Page

Foreword iv

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Requirements 1
4.1 General 1
4.2 Radio-detectability 1
4.3 Designation of nominal size 1
4.4 Physical requirements 2
4.5 Information to be supplied by the manufacturer 2

Annex A (normative) Test for balloon rated burst pressure (RBP) 3

Annex B (normative)Balloonfatiguetestforfreedomfromleakageanddamageoninflation 5

Annex C (normative)Testforballoondeflationtime 7

Annex D (normative)Testforballoondiametertoinflationpressure 9

Annex E (informative) Guidance on the selection of balloon materials 11

Bibliography 12