

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 Terms and definitions	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) Balloon fatigue test for freedom from leakage and damage on inflation	5
Annex C (normative) Test for balloon deflation time	7
Annex D (normative) Test for balloon diameter to inflation pressure	9
Annex E (informative) Guidance on the selection of balloon materials	11
Bibliography	12