ISO 10555-1:2013-06 (E)

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements

Contents

Page

Foreword iv

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Requirements 4
4.1 General 4
4.2 Radio-detectability 4
4.3 Biocompatibility 4
4.4 Surface 4
4.5 Corrosion resistance 4
4.6 Peak tensile force 4
4.7 Freedom from leakage 5
4.8 Hubs 5
4.9 Flowrate 5
4.10 Power injection 5
4.11 Side holes 5
4.12 Distal tip 5

5 Designation of nominal size 5
5.1 Outside diameter 5
5.2 Nominal effective length 6

6 Information to be supplied by the manufacturer 6
6.1 General 6
6.2 Marking on the device and/or primary packaging 6
6.3 Instructions for use 7
6.4 Marking on the secondary packaging 7

Annex A (normative) Test method for corrosion resistance 8

Annex B (normative) Method for determining peak tensile force 9

Annex C (normative) Test method for liquid leakage under pressure 11

Annex D (normative) Test method for air leakage into hub assembly during aspiration 13

Annex E (normative)Determinationofflowratethroughcatheter 15

Annex F (normative) Test for burst pressure under static conditions 17

Annex G (normative)Powerinjectiontestforflowrateanddevicepressure(onlyforproducts indicated for power injection) 19

Annex H (informative)Unitsofmeasurementsystemsotherthanthosespecifiedinthispartof Bibliography 24