DIN EN ISO 10555-1:2013-11 (E nglisch)

Intravascular catheters - Sterile and single-use catheters - Part 1: General req uirements (ISO 10555-1:2013)

Contents

Page

Foreword 3

1 Scope 4

2 Normative references 4

3 Terms and definitions 4

4 Requirements 7
4.1 General 7
4.2 Radio-detectability 7
4.3 Biocompatibility 7
4.4 Surface 7
4.5 Corrosion resistance 7
4.6 Peak tensile force 7
4.7 Freedom from leakage 8
4.8 Hubs 8
4.9 Flowrate 8
4.10 Power injection 8
4.11 Side holes 8
4.12 Distal tip 8

5 Designation of nominal size 8
5.1 Outside diameter 8
5.2 Nominal effective length 9

6 Information to be supplied by the manufacturer 9
6.1 General 9
6.2 Marking on the device and/or primary packaging 9
6.3 Instructions for use 10
6.4 Marking on the secondary packaging 10

Annex A (normative) Test method for corrosion resistance 11

Annex B (normative) Method for determining peak tensile force 12

Annex C (normative) Test method for liquid leakage under pressure 14

Annex D (normative) Test method for air leakage into hub assembly during aspiration 16

Annex E (normative) Determination of flowrate through catheter 18

Annex F (normative) Test for burst pressure under static conditions 20

Annex G (normative) Power injection test for flowrate and device pressure (only for products indicated for power injection) 22

Annex H (informative) Units of measurement systems other than those specified in this part of ISO 10555, which may additionally be used 25

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC amended by Directive 2007/47/EEC 27

Bibliography 29