

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

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