

# DIN EN ISO 10555-1:2018-04 (E)

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO 10555 -1:2013 + Amd 1:2017) (includes Amendment A1:2017)

Contents	Page
European foreword.....	4
[A1] European foreword to Amendment A1 [A1] .....	5
[A1] Foreword [A1] .....	6
[A1] Foreword to Amendment A1 [A1] .....	7
1 Scope.....	8
2 Normative references.....	8
3 Terms and definitions .....	8
4 Requirements .....	11
4.1 General.....	11
4.2 Radio-detectability.....	11
4.3 Biocompatibility .....	11
4.4 Surface.....	11
4.5 Corrosion resistance.....	11
4.6 Peak tensile force.....	11
4.7 Freedom from leakage .....	12
4.8 Hubs .....	12
4.9 Flowrate.....	12
4.10 Power injection.....	12
4.11 Side holes .....	12
4.12 Distal tip .....	12
5 Designation of nominal size .....	13
5.1 Outside diameter.....	13
5.2 Nominal effective length.....	13
6 Information to be supplied by the manufacturer.....	13
6.1 General.....	13
6.2 Marking on the device and/or primary packaging .....	13
6.3 Instructions for use .....	14
6.4 Marking on the secondary packaging.....	14
Annex A (normative) Test method for corrosion resistance.....	15
Annex B (normative) Method for determining peak tensile force .....	16
Annex C (normative) Test method for liquid leakage under pressure.....	18
Annex D (normative) Test method for air leakage into hub assembly during aspiration .....	20
Annex E (normative) Determination of flowrate through catheter .....	22
Annex F (normative) Test for burst pressure under static conditions.....	24
Annex G (normative) Power injection test for flowrate and device pressure (only for products indicated for power injection) .....	26

<b>Annex H (informative) Units of measurement systems other than those specified in this part of ISO 10555, which may additionally be used.....</b>	<b>29</b>
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC amended by Directive 2007/47/EEC .....</b>	<b>31</b>
<b>Bibliography .....</b>	<b>33</b>