

DIN EN ISO 10555-6:2020-02 (E)

Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports (ISO 10555-6:2015 + Amd 1:2019) (includes Amendment A1:2019)

Contents	Page
European foreword	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of Directive 93/42/EEC [O] L 169] aimed to be covered	4
A1 European foreword to Amendment A1 A1	7
Foreword	8
A1 Foreword to Amendment A1 A1	9
1 Scope	10
2 Normative references	10
3 Terms and definitions	10
4 Requirements of the implantable subcutaneous implanted port and catheter	12
4.1 General	12
4.2 Biocompatibility	13
4.3 Distance markings	13
4.4 Nominal dimensions of the subcutaneous implanted port	13
4.5 Physical requirements	13
4.5.1 Radio-detectability	13
4.5.2 Surface finish	13
4.5.3 Freedom from leakage	13
4.5.4 Flushing volume	13
4.5.5 Characteristics of the septum	14
4.5.6 Characteristics of the connection or the catheter	14
4.6 Flow rate	14
4.6.1 Subcutaneous implanted ports not indicated for power injection	14
4.6.2 Subcutaneous implanted ports indicated for power injection	14
4.7 Burst pressure of the subcutaneous implanted port and catheter	15
4.7.1 Subcutaneous implanted ports not indicated for power injection	15
4.7.2 Subcutaneous implanted ports indicated for power injection	15
5 Magnetic Resonance Imaging (MRI) compatibility	15
6 Information to be supplied by the manufacturer	15
6.1 Marking on the device	15
6.2 Primary packaging	15
6.3 Labels for traceability	16
6.4 Instruction for use	16
Annex A (normative) Test method for freedom from air leakage	17
Annex B (informative) Determination of flushing volume	18
Annex C (informative) Guidance on further characterization testing: Needle penetration and withdrawal	20
Annex D (normative) Test method for freedom from leakage after multiple punctures	22
Annex E (normative) Peak tensile force	23
Bibliography	24