

DIN EN ISO 7864:2016-12 (E)

Sterile hypodermic needles for single use - Requirements and test methods (ISO 7864:2016)

Contents

Page

European foreword	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] aimed to be covered	5
Foreword	7
Introduction	8
1 Scope	9
2 Normative references	9
3 Terms and definitions	9
4 Requirements	10
4.1 General	10
4.2 Statistics and reproducibility of test methods	10
4.3 Cleanliness	10
4.4 Limits for acidity or alkalinity	10
4.5 Limits for extractable metals	10
4.6 Size designation	11
4.6.1 Tubular needle designation	11
4.6.2 Tapered needle designation	11
4.7 Colour coding	12
4.8 Needle hub	12
4.8.1 Conical fitting	12
4.8.2 Colour of hub	12
4.9 Needle cap	12
4.10 Needle tube	13
4.10.1 General	13
4.10.2 Tolerances on length	13
4.10.3 Freedom from defects	14
4.10.4 Lubricant	14
4.11 Needle point	14
4.12 Bond between hub and needle tube	15
4.13 Patency of lumen	16
4.14 Sharps injury protection	17
4.15 Sterility and biocompatibility	17
4.15.1 Sterility	17
4.15.2 Biocompatibility	17
5 Packaging	17
5.1 Unit packaging	17
5.2 User packaging	18
6 Information supplied by the manufacturer	18
6.1 General	18
6.2 Unit packaging	18
6.3 User packaging	18
6.4 Storage container	19
6.5 Transport wrapping	20
Annex A (normative) Method for preparation of extracts	21
Annex B (informative) Fragmentation test for medical needles	22
Annex C (informative) Determination of flow rate through the needle	23
Annex D (informative) Test method for measuring the penetration force and drag force for needles	26
Annex E (informative) Needle bonding strength test method	30
Bibliography	32