

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