

DIN ISO 21881:2020-12 (E)

Sterile packaged ready for filling glass cartridges (ISO 21881:2019)

Contents

Page

National foreword	4
National Annex NA (informative) Bibliography	5
Foreword	7
Introduction	8
1 Scope	9
2 Normative references	9
3 Terms and definitions	9
4 Quality system	11
4.1 General	11
4.2 Testing	11
5 Process description and requirements	11
5.1 Washing	11
5.2 Drying	11
5.3 Lubrication	11
5.4 Capping and crimping	12
5.5 Plunger insertion	12
5.6 Packaging	12
5.7 Sterilization	12
6 Requirements for glassware	12
6.1 General	12
6.2 Material	12
6.3 Dimensions	13
6.4 Particles	13
6.4.1 Visible particles	13
6.4.2 Sub-visible particles	13
6.5 Bacterial endotoxin level	13
7 Requirements for packaging system	14
7.1 General	14
7.2 Nest and tub configuration	15
7.3 Tray configuration	15
7.4 Nest	15
7.5 Tub and tray	16
7.6 Insert liner	16
7.7 Sealing lid	16
7.8 Protective bag	16
7.9 Information to be provided by the manufacturer	17
8 Marking of the tub or tray	17
9 Labelling	18

Annex A (informative) Design of tub	19
Annex B (informative) Design of nest.....	20
Annex C (informative) Design of tray	21
Annex D (normative) Glide force test method to evaluate cartridge lubrication	22
Annex E (informative) Schematic illustrations of examples for the orientation of tubs or trays within the protective bag.....	24
Annex F (normative) Closure systems liquid leakage	27
Annex G (informative) Sample preparation for endotoxin and particulate determination	29
Annex H (informative) Product and packaging configuration.....	33
Bibliography	36