

ISO 9626:2016-08 (E)

Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Materials	2
5	Requirements	2
5.1	General	2
5.2	Surface finish and visual appearance	2
5.3	Cleanliness	2
5.4	Limits for acidity and alkalinity	2
5.5	Size designation	2
5.6	Dimensions	2
5.7	Sample size	5
5.8	Stiffness	5
5.9	Resistance to breakage	7
5.10	Resistance to corrosion	7
Annex A (normative) Methods for preparation of extracts		8
Annex B (normative) Test method for stiffness of tubing		9
Annex C (normative) Test method for resistance of tubing to breakage		11
Annex D (normative) Test method for resistance to corrosion		13
Annex E (informative) Rationale with respect to test method for stiffness of tubing		14
Bibliography		23