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 Termsanddefinitions 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