ISO 80369-6:2025-05 (E)

Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neural applications

Contents

Page

Foreword iv

Introduction vi

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Non-interconnectability requirements 2

5 Materials requirements 2

6 Dimensions and tolerances 2

7 Performance requirements 3
7.1 Positive pressure leakage 3
7.1.1 General 3
7.1.2 Leakage by pressure decay 3
7.1.3 Falling drop positive pressure liquid leakage 3
7.2 Sub-atmospheric pressure air leakage 3
7.3 Stress cracking 3
7.4 Resistance to separation from axial load 4
7.5 Resistance to separation from unscrewing 4
7.6 Resistance to overriding 4

Annex A (informative) Rationale and guidance 5

Annex B (normative) Dimensions and tolerances 7

Annex C (normative) Reference connectors for testing small-bore connectors for neural applications 16

Annex D (informative) Assessment of medical devices and their attributes with connections within this application 22

Annex E (informative) Reference to the IMDRF essential principles 23

Annex F (normative) Leakage by pressure decay test method 24

Annex G (normative) Subatmospheric-pressure air leakage test method 27

Annex H (informative)Alphabetizedindexofdefinedterms 30

Bibliography 31