

ISO 80369-3:2016-07 (E)

Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications

Contents	Page
Foreword	iv
Introduction	v
1 * Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements	3
4.1 General requirements for the enteral application	3
4.2 Material used for enteral small-bore connectors	3
4.3 Type tests	4
5 Dimensional requirements for enteral small-bore connectors	4
6 Performance requirements	4
6.1 Fluid leakage	4
6.1.1 Fluid leakage requirement	4
6.1.2 Leakage by pressure decay	4
6.1.3 Positive pressure liquid leakage	4
6.2 Stress cracking	4
6.3 Resistance to separation from axial load	4
6.4 Resistance to separation from unscrewing	5
6.5 Resistance to overriding	5
6.6 Disconnection by unscrewing	5
Annex A (informative) Rationale and guidance	6
Annex B (normative) Enteral small-bore connectors	10
Annex C (normative) Reference connectors	16
Annex D (informative) Assessment of medical devices and their attributes with connections within this application	21
Annex E (informative) Summary of the usability requirements for small-bore connectors for enteral applications	22
Annex F (informative) Summary of small-bore connector criteria and requirements for enteral applications	27
Annex G (informative) Summary of assessment of the design of the connectors for enteral applications	30
Annex H (informative) Reference to the essential principles	36
Annex I (informative) Terminology--Alphabetized index of defined terms	38
Bibliography	39