ISO 18250-3:2018 (E)

Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 3: Enteral applications

Contents

Foreword

Introduction

1 *Scope

2 Normative references

3 Terms and definitions

4 General requirements

4.1 non-interconnectable characteristics
4.2 *Materials

5 *Dimensional requirements

6 Performance requirements

6.1 General performance requirements
6.2 Positive pressure liquid leakage
6.3 Subatmospheric-pressure air leakage
6.4 Stress cracking
6.5 Resistance to separation from axial load
6.6 Resistance to separation from unscrewing
6.7 Resistance to overriding
6.8 Disconnection by unscrewing

Annex A (informative) Rationale and guidance

A.1 General
A.2 Rationale for particular clauses and subclauses

Annex B (normative) enteral reservoir connectors

Annex C (normative) Reference connectors

C.1 General requirements for reference connectors
C.2 Reference connectors

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

Annex E (informative) Summary of the usability requirements for reservoir connectors for enteral applications

E.1 User profile
E.2 Use scenarios
E.3 Use environments
E.3.1 Facilities
E.3.2 Use temperature
E.4 Other attributes
E.5 Generic user needs

Annex F (informative) Summary of reservoir connector criteria and requirements for enteral applications

Annex G (informative) Summary of assessment of the design of the reservoir connectors for enteral applications

G.1 General
G.2 Summary of the engineering analysis of the design
G.3 Summary of the design verification
G.4 Summary of the design validation
G.5 Summary of the design review

Annex H (informative) Deviations from ISO 80369-20

Annex I (informative) Twist-lock connector geometric layout and functioning

Page count: 39