ISO 18250-8:2018 (E)

Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 8: Citrate-based anticoagulant solution for apheresis applications

Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 General requirements

- 4.1 Non-Interconnectability through conformance to ISO 18250-8
- 4.2 *Materials
- 4.3 Apheresis AC reservoir connector Descriptions
- 4.4 *Design
- 4.5 Reference connectors

5 Performance requirements

- 5.1 General
- 5.2 *Positive pressure liquid leakage
- 5.3 Stress-cracking
- 5.4 Resistance to separation from axial load
- 5.5 Resistance to separation from unscrewing
- 5.6 Resistance to overriding
- 5.7 *Subatmospheric pressure air leakage

Annex A (informative) Rationale and guidance

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

Annex B (normative) connectors drawings and dimensions

Annex C (normative) Reference connectors

Annex D (informative) Summary of assessment of the design of the apheresis AC reservoir connectors

- D.1 CAD Process

Page count: 24