

# ISO 18250-7:2018-12 (E)

## Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 7: Connectors for intravascular infusion

---

| <b>Contents</b>   | <b>Page</b> |
|---|-------------|
| Foreword .....  | iv          |
| Introduction .....  | vi          |
| 1 *Scope .....  | 1           |
| 2 Normative references .....  | 1           |
| 3 Terms and definitions .....   | 2           |
| 4 General requirements .....  | 2           |
| 4.1 Non-interconnectability through conformance to this document .....  | 2           |
| 4.2 * Intravascular Reservoir Connector types .....   | 2           |
| 5 Material requirements .....   | 3           |
| 5.1 Connector Type 1: spikes and administration ports .....   | 3           |
| 5.2 Connector Type 2: Luers .....   | 3           |
| 6 Dimensional requirements .....  | 3           |
| 6.1 Connector Type 1: Spikes and Administration Ports .....   | 3           |
| 6.2 Connector Type 2: Luers .....   | 3           |
| 7 Performance requirements .....  | 3           |
| 7.1 * Connector Type 1: Spikes and Administration Ports .....   | 3           |
| 7.2 Connector Type 2: Luers .....   | 3           |
| Annex A (informative) Rationale and guidance .....  | 4           |
| Annex B (normative) Design of connectors* .....   | 13          |
| Annex C (informative) Assessment of reservoir connectors and their attributes with connections to medical devices within this intravascular application ..... | 15          |
| Annex D (informative) Summary of usability and requirements for connectors for intravascular reservoirs .....   | 16          |
| Annex E (informative) Summary of reservoir connector design requirements for intravascular infusion .....   | 19          |
| Annex F (informative) Summary of engineering analysis and residual misconnections for connectors for intravascular reservoirs .....                           | 24          |
| Annex G (informative) Alternative spikes .....  | 30          |
| Bibliography .....  | 34          |