

ISO 80369-7:2021 (E)

Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

Contents

	Foreword	
	Introduction	
1	Scope	
2	Normative references	
3	Terms and definitions	
4	General requirements	
4.1	General requirements for Luer connectors	
4.2	Type tests	
5	Dimensional requirements for Luer connectors	
6	Performance requirements	
6.1	Fluid leakage	
6.1.1	Fluid leakage requirement	
6.1.2	Leakage by pressure decay	
6.1.3	Positive pressure liquid leakage	
6.2	Sub-atmospheric pressure air leakage	
6.3	Stress cracking	
6.4	Resistance to separation from axial load	
6.5	Resistance to separation from unscrewing	
6.6	Resistance to overriding	
Annex A	(informative) Rationale and guidance	
A.1	General guidance	
A.2	Rationale for particular clauses and subclauses	
Annex B	(normative) Luer 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 Luer connectors for intravascular or hypodermic 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 Luer connector design requirements for intravascular or hypodermic applications	

Annex G (informative) Summary of assessment of the design of the Luer connector for intravascular or hypodermic applications

- G.1 General**
- G.2 Summary of the engineering analysis of the design**
 - G.2.1 Non-interconnectable analysis**
 - G.2.2 Luer connector male to N1 male**
 - G.2.3 Luer slip connector female to E1 female**
 - G.2.4 Luer slip connector female to N2 male lock**
- G.3 Summary of the design verification**
- G.4 Summary of the design validation**
- G.5 Summary of the design review**

Annex H (informative) Reference to the essential principles

Annex I (informative) Reference to the general safety and performance requirements

Annex J (informative) Terminology — Alphabetized index of defined terms

Page count: 47