

DIN EN ISO 80369-7:2021-08 (E)

Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)

Contents	Page
European foreword	3
Foreword	4
Introduction	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	7
4 General requirements	8
4.1 General requirements for <i>Luer connectors</i>	8
4.2 Type tests	8
5 Dimensional requirements for <i>Luer connectors</i>	8
6 Performance requirements	9
6.1 Fluid leakage	9
6.1.1 Fluid leakage requirement	9
6.1.2 Leakage by pressure decay	9
6.1.3 Positive pressure liquid leakage	9
6.2 Sub-atmospheric pressure air leakage	9
6.3 Stress cracking	10
6.4 Resistance to separation from axial load	10
6.5 Resistance to separation from unscrewing	10
6.6 Resistance to overriding	10
Annex A (informative) Rationale and guidance	11
Annex B (normative) <i>Luer connectors</i>	15
Annex C (normative) Reference connectors	30
Annex D (informative) Assessment of <i>medical devices</i> and their attributes with <i>connections</i> within this <i>application</i>	37
Annex E (informative) Summary of the usability requirements for <i>Luer connectors</i> for intravascular or hypodermic applications	39
Annex F (informative) Summary of <i>Luer connector</i> design requirements for intravascular or hypodermic applications	43
Annex G (informative) Summary of assessment of the design of the <i>Luer connector</i> for intravascular or hypodermic applications	46
Annex H (informative) Reference to the essential principles	49
Annex I (informative) Reference to the general safety and performance requirements	50
Annex J (informative) Terminology — Alphabetized index of defined terms	51
Bibliography	52