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NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

YY/T 0916.7-2024

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

医用液体和气体用小孔径连接件 第7部分：血管内或皮下应用连接件

Issued on: July 8, 2024 **Implemented on: July 20, 2026**

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Foreword

This document was issued on 8 July 2024 by the National Medical Products Administration and takes effect on 20 July 2026.

It is a YY/T standard: it is recommended rather than compulsory, but it is the method a Chinese reviewer applies when assessing a registration submission.

1 Scope

YY/T 0916.7 is the Chinese adoption of the small-bore connector standard for intravascular and hypodermic use, the part of the ISO 80369 family that governs the Luer-type connection. Its purpose is to make wrong-route connections physically impossible: a family of incompatible geometries so that an enteral line cannot be joined to an intravenous one, a class of error that has killed patients and that no amount of labelling had prevented. At 32,760 words it is one of the longest documents in the series, because the geometry has to be specified to a tolerance that guarantees both connection and non-connection. It is cited normatively by device standards including YY 0781 on blood pressure transducers. For any manufacturer of infusion, injection or vascular access devices for China, this is a governing connector standard.

This document specifies the dimensions and requirements for the design and functional characteristics of small-bore connectors, which are intended for use in connections for intravascular applications or hypodermic injection applications involving medical devices and accessories. Examples. Hypodermic syringes and needles or intravascular (hereinafter referred to as IV) cannulae with male and female Luer non-locking (slip) connectors and Luer-lock connectors.

Note 1: See Appendix A.

Note 2: Luer connectors were originally designed for pressures not exceeding 300 kPa. This document does not specify requirements for medical devices or accessories that use these connectors. Such requirements are provided in specific documents for particular medical devices or accessories. This document does not specify requirements for small-bore connectors specified in the following other documents. - Blood compartment ports of hemodialyzers, hemodiafilters, hemofilters (relevant parts of ISO 8637 and ISO 8638 regarding blood compartment ports); - Connectors for hemodialysis, hemodiafiltration, hemofiltration equipment (ISO 8637); - Spike connectors for infusion systems (ISO 8536-4).

Note 3: Manufacturers are encouraged to incorporate small-bore connectors complying with this document into medical devices or accessories, even if current specific documents for those medical devices do not require it. It is anticipated that when relevant specific medical device documents are revised, the requirements for small-bore connectors

specified in YY/T 0916 will be included.

Note 4: Chapter 7 of YY/T 0916.1-2021 specifies alternative methods for small-bore connectors intended for use with medical devices or accessories for intravascular or hypodermic applications; these connectors comply with YY/T 0916.1-2021 but do not comply with this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

YY/T 0916.1-2021 Small bore connections for medical liquids and gases - Part 1. General requirements (ISO 80369-1.2018, IDT)

YY/T 0916.6-2022 Small bore connectors for medical liquids and gases - Part 6. Connectors for axonal applications (ISO 80369-6.2016, IDT)

YY/T 0916.20-2019 Small bore connections for medical liquids and gases - Part 20. General test methods (ISO 80369-20.2015, IDT)

ISO 14971.2019 Medical devices - Application of risk management to medical devices Note.

GB/T 42062-2022 Medical devices - Application of risk management to medical devices

IEC 62366-1.2015 Medical devices - Part 1: Application of usability engineering to medical devices Note.

YY/T 1474-2016 Application of medical device usability engineering to medical devices (IEC 62366.2007, IDT)

3 Terms and definitions

The terms and definitions defined in YY/T 0916.1-2021, YY/T 0916.20-2019, ISO 14971.2019, IEC 62366-1.2015 (as shown in Appendix J), as well as the following terms and definitions, apply to this document.

3.1 Auxiliary dimension Dimension derived from other dimensions, provided for reference only. [Source. ISO 10209.2012, 4.2] 3.2 [Source. IEC 60601-1.2005, 3.97]

3.7 Rigid material Material with a flexural modulus or tensile modulus greater than 3433 MPa. Examples. Metals, glass, certain fiber-reinforced polymers, high-performance polymers.

3.8 Semi-rigid material Material with a flexural modulus or tensile modulus 700 MPa ~ 3433 MPa. Example. Thermoplastics.

4 General requirements

4.1 General requirements for Luer connectors Luer connectors intended to be manufactured in accordance with this document shall comply with the general requirements of YY/T 0916.1-2021, unless otherwise specified in this document. In some tolerance fits, at the least material condition (LMC), the inner diameter of the fluid lumen of a male Luer connector may contact the sealing surface of the N1 male connector (N1) specified in YY/T 0916.6-2022; consequently, these connectors may misconnect when evaluated against the non-interconnectable characteristics test in Appendix B of YY/T 0916.1-2021: Additional information is provided in G.2.2. Reference connectors for evaluating non-interconnectable characteristics are described in Appendix C (Figures C.1, C.2, C.4, C.5, as appropriate). If the design of a medical device or accessory provides the characteristics of the Luer connectors specified in this document, these characteristics shall be included in the verification of compliance with this document. Where necessary, small-bore connectors shall be fitted to the medical device or accessory to verify compliance with Appendix B of YY/T 0916.1-2021.

Note 1: A summary of medical devices incorporating these connectors and their attributes is provided in Appendix D.

Note 2: A summary of usability requirements for Luer connectors is provided in Appendix E.

Note 3: A summary of criteria and requirements for Luer connectors is provided in Appendix F.

Note 4: A summary of design assessment for Luer connectors in accordance with 6.1 of YY/T 0916.1-2021 is provided in Appendix G.

Note 5: This document is intended to address the relevant essential principles of safety and performance of ISO 16142-1.2016, as shown in Appendix H.

Note 6: This document is intended to address the relevant general safety and performance requirements of EU Regulation (EU) 2017/745, as shown in Appendix I.

4.2 Type testing Compliance with the requirements of this document shall be determined through type testing.

5 Dimensional design requirements for Luer connectors

Luer connectors shall comply with the dimensional and tolerance requirements specified below. - Male Luer non-locking (slip) connector (L1). Figure B.1 and Table B.1; - Female Luer non-locking (slip) connector (L1). Figure B.2 and Table B.2; - Male Luer lock connector with fixed collar (L2). Figure B.3 and Table B.3; - Male Luer lock connector with movable or rotatable collar (L2). Figure B.4 and Table B.4; - Female Luer lock connector (L2). Figure B.5 and Table B.5; - Female Luer lock connector (L2) Type A with lugs