

YY

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0948-2025

**Cardiopulmonary bypass systems - Arteriovenous cannula for
single use**

心肺转流系统 一次性使用动静脉插管

Issued on: June 18, 2025

Implemented on: July 1, 2028

Issued by: National Medical Products Administration

Table of Contents

Foreword

1 Scope

2 Normative references

3 Terms and definitions

About this edition

Classification and status

How a Chinese national standard is set out

About this English translation

Foreword

This document was issued on 18 June 2025 by the National Medical Products Administration and takes effect on 1 July 2028.

It is a YY standard without the /T suffix: compliance is mandatory in China.

1 Scope

YY 0948 is the mandatory standard for the single-use arteriovenous cannula in a cardiopulmonary bypass circuit, the tube that takes blood out of the patient and returns it during open heart surgery. As a YY standard without the /T suffix, compliance in China is compulsory. The cannula is the part of the bypass circuit in direct contact with the great vessels and under full pump pressure, so its dimensional accuracy, kink and burst behaviour, connection security and blood contact properties are what the standard has to fix. The 2025 edition takes effect on 1 July 2028, a three-year transition consistent with the other mandatory implant and circuit standards issued that day. For a manufacturer or an importer of bypass cannulae selling into China, this is the governing document.

About this edition

YY 0948-2025 is the current edition. It was issued on 18 June 2025 and has been in force since 1 July 2028.

The interval between issue and effect is the transition period. It exists so that producers, laboratories and buyers can requalify products, revise procedures and use up documentation before the new text becomes the one that applies. The date on this page is the official one from the record of the Standardization Administration.

Classification and status

The YY prefix marks an industry standard, issued by the authority for its sector rather than by the national body. It applies within that industry, and it becomes binding in the same ways a recommended national standard does: when a contract, a regulation or a declaration of conformity names it.

How a Chinese national standard is set out

Chinese national standards are drafted to the rules of GB/T 1.1, which fixes the order in which a standard is set out. The document opens with a foreword recording the issuing bodies, the relationship to any previous edition and the technical committee responsible for it. Clause 1 is the scope. Clause 2 lists the normative references - the other standards that have to be applied together with this one, and without which its requirements cannot be met. Clause 3 gives the terms and definitions. The technical clauses follow: the requirements themselves, the test or measurement methods by which conformity is established, the inspection rules that say how a lot is sampled and judged, and, for a product standard, the provisions on marking, packaging, transport and storage. Annexes, normative or informative, come last.

YY 0948-2025 runs to 27 pages in the English translation. What is delivered is the complete document in that order: every clause, every table, every figure and every annex of the Chinese original, with the same numbering, so that a reference to a clause number in a contract or a test report points to the same place in both languages.

About this English translation

The English edition of YY 0948-2025 is a full translation of the official Chinese text, not a summary, an abstract or a machine rendering left unchecked. Clause and subclause numbers, table and figure numbers and annex letters are those of the original, because they are what a specification, a purchase order or a test report cites.

Technical terms are translated against the vocabulary standards of the same field, so that a term used in YY 0948-2025 reads the same way as in the other Chinese standards it is used beside. Where a term has an established English form in an ISO or IEC document on the same subject, that form is used; where China's term has no foreign counterpart, it is translated literally and the Chinese is kept alongside it rather than replaced by an approximation.

Quantities, units and symbols are carried over unchanged. Chinese standards use SI, so a value in the translation is the value in the original document, not a conversion, and a limit read from the English text is the limit that will be applied by a Chinese inspection body reading the Chinese one.

This page is compiled from the official publication record: the standard number and both titles, the issuing bodies, the dates of issue and effect. The requirements, limits, tables and test conditions are in the document itself.

chinastandards.org - PREVIEW