INTERNATIONAL STANDARD

国际标准

Second edition

第2版

2016-08-1

Stainless steel needle tubing for the manufacture of medical devices —Requirements and test methods

医疗器械制造用不锈钢针管要求和试验方法

(中英文版)

2024年05月翻译

Reference number

ISO 9626:2016(E)

目录

Foreword

前言

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

ISO（国际标准化组织）是一个由国家标准机构（ISO成员机构）组成的世界性联合会。编制国际标准的工作通常通过ISO技术委员会进行。对已成立技术委员会的主题感兴趣的每个成员机构都有权在该委员会中派代表。与国际标准化组织联络的政府和非政府国际组织也参加了这项工作。

ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

ISO与国际电工委员会（IEC）在电工技术标准化的所有事项上密切合作。

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO/IEC指令第1部分描述了用于编制本文件的程序以及用于进一步维护的程序。尤其应注意不同类型ISO文件所需的不同批准标准。本文件是根据ISO/IEC指令第2部分的编辑规则起草的（见www.iso.org/directives）。

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

请注意，本文件的某些内容可能是专利权的主题。ISO不承担识别任何或所有此类专利权的责任。在文件开发过程中确定的任何专利权的详细信息将在引言和/或收到的ISO专利声明列表中（见www.iso.org/patents）。

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

本文件中使用的任何商品名称都是为了方便用户而提供的信息，不构成背书。

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO’ s adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

关于与合格评定相关的ISO特定术语和表达的含义的解释，以及关于ISO在技术性贸易壁垒（TBT）中遵守WTO原则的信息，请参阅以下URL：前言-补充信息。

The committee responsible for this document is ISO/TC 84, Devices for administration of medicinal products and catheters.

负责本文件的委员会是ISO/TC 84，药品和导管管理装置。

This second edition cancels and replaces the first edition (ISO 9626:1991), which has been technically revised. It also incorporates the Amendment ISO 9626:1991/Amd 1:2001.