Form 36

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Interested committees:

Title: Draft BS EN ISO 9626 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/ Figure/Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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DRAFT International Standard

ISO/DIS 9626

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

Tubes d'aiguilles en acier inoxydable pour la fabrication de matériel médical — Exigences et méthodes d'essai

ICS: 11.040.25

ISO/TC **84**

Secretariat: **DS**

Voting begins on:
2025-11-24

Voting terminates on:
2026-02-16

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

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Foreword

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

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 draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee 84, *Devices for administration of medicinal products and catheters*.

This third edition cancels and replaces the second edition (ISO 9626:2016), which has been technically revised.

The main changes are as follows:

— included requirement statistics and reproducibility of test methods as mentioned in ISO 7864;

— harmonized illumination requirements for tests 5.3 and 5.4 based on relevant standards;

— closed gaps in dimensions of tubings (Table 1);

— defined visible breakage;

— re-defined Annex C (Test method for resistance of tubing to breakage);

— deleted RW=Regular Wall, TW=Thin Wall, ETW= Extra Thin Wall, and UTW=Ultra-Thin Wall.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

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

1 Scope

This document applies to rigid stainless steel needle tubing suitable for use in the manufacture of hypodermic needles and other medical devices primarily for human use.

This document provides requirements and test methods for the tubes manufactured for needles as component used in medical devices. Additional performance testing on the tube aspect may be required when the component is incorporated in the ready-to-use device.

This document specifies the dimensions and mechanical properties of steel tubing of designated metric sizes 3,4 mm (10 Gauge) to 0,18 mm (34 Gauge).

It does not apply to flexible stainless steel tubing because the mechanical properties differ from those specified for rigid tubing in this document. However, manufacturers and purchasers of flexible tubing are encouraged to adopt the dimensional specifications given in 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.

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 15510, *Stainless steels — Chemical composition*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
designated metric size
outer diameter designation of the tubing as defined in Table 1

Note 1 to entry: It is expressed in millimetres.

3.2
gauge
legacy size designation; a particular gauge size corresponds to a designated metric size defining limits for outer diameters.

3.3
wall thickness
material thickness between the inner and outer diameter of the tube

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