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Interested committees:

Title: Draft BS EN ISO 7864 Sterile hypodermic needles for single use — 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.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (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.	



DRAFT International Standard

ISO/DIS 7864

Sterile hypodermic needles for single use — Requirements and test methods

Aiguilles hypodermiques stériles, non réutilisables — Exigences et méthodes d'essai

ICS: 11.040.25

ISO/TC 84

Secretariat: **DS**

Voting begins on:
2025-11-25

Voting terminates on:
2026-02-17

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).

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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 ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This fifth edition cancels and replaces the fourth edition (ISO 7864:2016), which has been technically revised.

The main changes are as follows:

- Harmonized designated sizes with ISO 9626;
- Included term and explanation for coating, lubrication and non-permanent coating;
- Harmonized illumination requirements for tests [4.3](#) based on relevant standards;
- Changed size designation from inner diameter to flow rate;
- Updated colour coding;
- Updated length tolerance;
- Updated requirement for bonding between hub and needle tube;
- Combined patency of lumen with flow properties;
- Updated [Annex D](#) Test method of measuring the penetration force and friction force for needle.

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.

Introduction

This document covers sterile hypodermic needles for single use intended to inject or withdraw fluids from primarily the human body.

Plastics materials to be used for the construction of needles are not specified, as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers.

Hypodermic needles specified in this document are intended for use with syringes having a 6 % Luer conical fitting as specified in ISO 80369-7 in conjunction with ISO 80369-1 and ISO 80369-20.

Devices/connectors intended to mate with hypodermic needles of the document, but which deviate from ISO 80369-7 shall provide demonstrated evidence of safe functional performance.

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

Sterile hypodermic needles for single use — Requirements and test methods

1 Scope

This document specifies requirements for sterile hypodermic needles for single use of designated metric sizes 0,18 mm to 3,4 mm.

It does not apply to those devices that are covered by their own standard such as dental needles and pen needles.

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 6009, *Hypodermic needles for single use — Colour coding for identification*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 9626:xxxx¹⁾, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 23908, *Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods*

ISO 80369-1, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neural applications*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

3 Terms and definitions

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

1) Currently subject to revision (to be submitted as DIS in October 2025)

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

coating

measurable layer of material added onto the outer surface of the needle that is intended to be permanent and not come off during use

Note 1 to entry: The purpose of applying the coating may be decorative, functional (e.g. improve electrical connectivity, reduce friction etc.) or both.

3.2

gauge

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

3.3

lubrication

application of a liquid coating or solid coating intended to reduce friction and wear between two elements that move relative to each other (e.g. needle and skin or other substrates into which the needle is inserted)

3.4

needle cap

cover intended to physically protect the *needle tube* (3.6) prior to use

3.5

needle hub

tbd

Drafting note: Proposals for definition requested during enquiry procedure.

3.6

needle tube

tbd

Drafting note: Proposals for definition requested during enquiry procedure.

3.7

non-permanent coating

substance applied to the surface of a needle that can be removed by normal use of the needle

Note 1 to entry: Liquid lubricant such as silicone.

3.8

tapered needle

needle with conical needle tube which has an outer diameter spanning at least two consecutive designated metric sizes

3.9

unit packaging

packaging of an individual device, intended to maintain its sterility

3.10

user packaging

packaging, which contains one or more items of unit *packaging* (3.9), designed to provide labelling information to the user