

Sterile hypodermic needles for single use

The European Standard EN ISO 7864:1995 has the status of a
British Standard

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/2, upon which the following bodies were represented:

- Association of British Health Care Industries
- Association of Clinical Pathologists
- British Diabetic Association
- British Glass Manufacturers' Confederation
- British Surgical Trades Association
- Department of Health
- Disposable Hypodermic and Allied Equipment Manufacturers' Association (UK)
- Medical Sterile Products Association
- Royal Pharmaceutical Society of Great Britain
- Co-opted members

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 November 1993

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with ISO 7864:1993, *Sterile hypodermic needles for single use*, published by the International Organization for Standardization (ISO). It supersedes BS 5081-2:1987 which is withdrawn.

In 1995, the European Committee for Standardization (CEN) accepted ISO 7864:1993 as European Standard EN ISO 7864:1995. As a consequence of implementing the European Standard, this British Standard is renumbered as BS EN ISO 7864:1996.

BS 5081 was first published in 1976 and specified requirements for sterile hypodermic syringes and needles for single use. A two-part revision was published in 1987, Part 1 covering sterile, single-use hypodermic syringes and Part 2 covering sterile single-use hypodermic needles.

Hypodermic needles specified in this Part of BS 5081 are suitable for use with hypodermic syringes specified in BS 5081-1:1987, which is expected to be revised by implementing the revision of ISO 7886:1984, currently in preparation. The needles will also fit with the syringes specified in BS 1263, BS 1619 and BS 7548.

Cross-references

International standard	Corresponding British Standard
	BS 3930 <i>Conical fittings with a 6 % (Luer) taper for syringes, needles and other medical equipment</i>
ISO 594-1:1986	Part 1:1987 <i>Specification for general requirements</i> (Identical)
ISO 594-2:1991	Part 2:1991 <i>Specification for lock fittings</i> (Identical)
ISO 3696:1987	BS 3978:1987 <i>Specification for water for laboratory use</i> (Identical)
ISO 6009:1992	BS 7128:1993 <i>Specification for colour coding of hypodermic needles for single use</i> (Identical)
ISO 8601:1988	BS EN 28601:1992 <i>Specification for representation of dates and times in information interchange</i> (Identical)
ISO 9626:1991	BS 7547:1991 <i>Specification for stainless steel needle tubing for the manufacture of medical devices</i> (Identical)

The Technical Committee has reviewed the provisions of ISO 7886-1 to which reference is made in the text and has decided that they are acceptable for use in conjunction with this Part of BS 5081. It is expected that ISO 7886-1 (revision of ISO 7886:1984), when published, will be implemented as a revision of BS 5081-1:1987.

It is recommended that needles be manufactured and sterilized in accordance with the recommendations in *Quality systems for sterile medical devices and surgical products 1990. Good manufacturing practice*¹⁾.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN ISO title page, pages 2 to 12, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

¹⁾ Published by the Department of Health and Social Security, and available from HMSO, 49 High Holborn, London WC1 for personal callers, or by post from HMSO, P.O. Box 276, London SW8 5DT.

