

Sterile hypodermic syringes for single use —

Part 1: Syringes for manual use

The European Standard EN ISO 7886-1:1997 has the status of a British Standard

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National foreword

This British Standard is the English language version of EN ISO 7886-1:1997. It is identical with ISO 7886-1:1993 including Technical Corrigendum 1, November 1995. It supersedes BS 5081-1:1994 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/2, Hypodermic equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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 and ii, the EN ISO title page, page 2, the ISO title page, pages ii to iv, pages 1 to 18 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.

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 September 1997

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English version

Sterile hypodermic syringes for single use — Part 1: Syringes for manual use

(ISO 7886-1:1993, including Technical Corrigendum 1:1995)

Seringues hypodermiques stériles, non réutilisables — Partie 1: Seringues pour utilisation manuelle (ISO 7886-1:1993, Rectificatif Technique 1:1995 inclus)

Sterile Einmalspritzen für medizinische Zwecke — Teil 1: Spritzen zum manuellen Gebrauch (ISO 7886-1:1993, einschließlich Technische Korrektur 1:1995)

This European Standard was approved by CEN on 1997-02-28. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

The text of the International Standard from ISO/TC 84 “*Medical devices for injections*” of the International Organization for Standardization (ISO) has been taken over as a European Standard by the Technical Committee CEN/TC 205 “*Non-active medical devices*”, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 1997, and conflicting national standards shall be withdrawn at the latest by November 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 7886-1:1993, including Technical Corrigendum 1:1995, has been approved by CEN as a European Standard without any modification.

NOTE Normative references to international publications are listed in Annex ZA (normative).

INTERNATIONAL STANDARD

ISO 7886-1

First edition
1993-10-01

Sterile hypodermic syringes for single use —

Part 1: Syringes for manual use

*Seringues hypodermiques stériles, non réutilisables —
Partie 1: Seringues pour utilisation manuelle*



Reference number
ISO 7886-1:1997



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Descriptors: Medical equipment, disposable equipment, syringes, specifications, dimensions, tests, packaging, labelling.

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 7886-1 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Sub-Committee SC 1, *Syringes, needles and intravascular catheters for single use*.

This first edition of ISO 7886-1 cancels and replaces ISO 7886:1984. It was decided to divide the Standard into two parts, ISO 7886-1 retaining essentially the scope of ISO 7886:1984, and ISO 7886-2 (in course of preparation) being applicable to sterile, single-use syringes for use with power-driven syringe pumps. The major differences between this part of ISO 7886 and ISO 7886:1984 are as follows.

- a) In order to reflect the demand for syringes of sizes other than those listed in ISO 7886:1984, this part of ISO 7886 does not specify a range of syringe sizes and allows the syringes to be marked with graduations at greater than the nominal capacity.
- b) An informative annex on forces required to operate the syringe plunger has been introduced.
- c) The tests for toxicity given in ISO 7886:1984 have been replaced by an informative cross-reference to ISO 10993-1.
- d) The informative annex on test methods for compatibility between syringes and injection fluids has been revised.
- e) This part of ISO 7886 permits the use on package labelling of the ISO symbol for “do not re-use”, but continues to require the written word. Manufacturers are encouraged to use the symbol so as to increase familiarity with it among purchasers and users.

ISO 7886 consists of the following parts, under the general title *Sterile hypodermic syringes for single use*:

- *Part 1: Syringes for manual use;*
- *Part 2: Syringes for use with syringe pumps.*

Annex A, Annex B, Annex C and Annex D form an integral part of this part of ISO 7886. Annex E, Annex F, Annex G, Annex H and Annex J are for information only.