

Transfusion equipment for medical use —

Part 4: Transfusion sets for single use

The European Standard EN ISO 1135-4:2004 has the status of a
British Standard

ICS 11.040.20

National foreword

This British Standard was published by BSI. It is the UK implementation of EN ISO 1135-4:2004. It is identical with ISO 1135-4:2004. Together with BS EN ISO 3826-1:2003 and BS ISO 3826-3:2006, it supersedes BS 2463-1:1990 and BS 2463-2:1989 which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on CH/212 can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

Amendments issued since publication

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English version

Transfusion equipment for medical use - Part 4: Transfusion
sets for single use (ISO 1135-4:2004)

Matériel de transfusion à usage médical - Partie 4:
Appareils de transfusion non réutilisables (ISO 1135-
4:2004)

Transfusionsgeräte zur medizinischen Verwendung - Teil 4:
Transfusionsgeräte zur einmaligen Verwendung (ISO 1135-
4:2004)

This European Standard was approved by CEN on 22 June 2004.

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.

This European Standard exists 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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Foreword

This document (EN ISO 1135-4:2004) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" in collaboration with 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 January 2005, and conflicting national standards shall be withdrawn at the latest by January 2005.

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

Endorsement notice

The text of ISO 1135-4:2004 has been approved by CEN as EN ISO 1135-4:2004 without any modifications.

INTERNATIONAL STANDARD

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Transfusion equipment for medical use — Part 4: Transfusion sets for single use

Matériel de transfusion à usage médical —

Partie 4: Appareils de transfusion non réutilisables



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 1135-4 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 1135-4:1998), which has been technically revised.

ISO 1135 consists of the following parts, under the general title *Transfusion equipment for medical use*:

- *Part 3: Blood-taking set*
- *Part 4: Transfusion sets for single use*