

INTERNATIONAL STANDARD

ISO
1135-1

Second edition
1987-11-01



INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Transfusion equipment for medical use —

Part 1: Glass transfusion bottles, closures and caps

Matériel de transfusion à usage médical —

Partie 1: Flacons de transfusion en verre, bouchons et capsules

Reference number
ISO 1135-1:1987 (E)



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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 1135-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

This second edition of ISO 1135-1 cancels and replaces the first edition of ISO 1135-1 : 1986, of which it constitutes a minor revision.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Transfusion equipment for medical use —

Part 1:

Glass transfusion bottles, closures and caps

1 Scope and field of application

This part of ISO 1135 specifies dimensions and requirements for types of transfusion bottles for medical use in order to ensure functional interchangeability of the equipment.

Secondary aims of this part of ISO 1135 are to provide

- a) specifications relating to the quality and performance of materials used in transfusion equipment;
- b) a unified presentation of terms and designations for such equipment.

Transfusion bottles with rubber closures should not yield, in normal conditions of use, substances having undesirable effects on the contents or producing harmful effects on the patient receiving the contents. No tests have yet been developed to assess these effects and therefore no requirements have been included.

This part of ISO 1135 specifies requirements applicable to sterilized glass transfusion bottles for single use.

2 References

ISO 718, *Laboratory glassware — Methods for thermal shock tests.*

ISO 719, *Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification.*

ISO 3302, *Rubber — Dimensional tolerances of solid moulded and extruded products.*

ISO 4802, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers —*

Part 1: Determination by titration method and classification.

Part 2: Determination by flame spectrometric methods and classification.

ISO 7458, *Glass containers — Internal pressure resistance test — Test methods.*

ISO 8872, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods.*¹⁾

1) At present at the stage of draft.