INTERNATIONAL STANDARD

**ISO 15747**

Second edition
2010-04-15

# Plastic containers for intravenous injections

*Récipients en plastique pour injections intraveineuses*

Reference number
ISO 15747:2010(E)



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Published in Switzerland

 

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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 15747 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 15747:2003), which has been technically revised. Especially Annex C was totally revised in order to refer to the International Standards of the ISO 10993 series, which specifies the biological assessment of medical products.



 

## Introduction

In some countries, national or regional pharmacopoeias or other government regulations are legally binding and these requirements take precedence over this International Standard.

# Plastic containers for intravenous injections

## 1 Scope

This International Standard contains requirements that relate to the safe handling and the physical, chemical and biological testing of plastic containers for parenterals.

This International Standard is applicable to plastic containers for parenterals having one or more chambers and having a total nominal capacity in the range of 50 ml to 5 000 ml such as film bags or blow-moulded plastic bottles for direct administration of infusion (injection) solutions.



## 2 Normative references

The following referenced documents are indispensable for the application 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 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

ISO 10993 (all parts), *Biological evaluation of medical devices*

## 3 Terms and definitions

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

**3.1**
**access port**
area of the infusion container consisting of the insertion point and the injection point, if applicable

**3.2**
**cover**
part that protects the access port during storage and also provides evidence that the infusion container has been tampered with

NOTE The cover can also envelop the entire container (e.g. outer bag).

**3.3**
**empty container**
raw container with identification, which is suitable for the acceptance, storage and administration of the injection solution

**3.4**
**hanger**
that part of the container that is used to hang it up