Fourth edition
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Infusion equipment for medical use —

Part 1:
Infusion glass bottles

Matériel de perfusion à usage médical —

Partie 1: Flacons en verre pour perfusion

Reference number
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Foreword

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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 8536-1 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This fourth edition cancels and replaces the third edition (ISO 8536-1:2006), of which it constitutes a minor revision.

The principle changes to the third edition are the updating of normative references to ISO 4802-1 and ISO 4802-2, and the addition of a note at the start of Clause 8.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

— *Part 1: Infusion glass bottles*

— *Part 2: Closures for infusion bottles*

— *Part 3: Aluminium caps for infusion bottles*

— *Part 4: Infusion sets for single use, gravity feed*

— *Part 5: Burette infusion sets for single use, gravity feed*

— *Part 6: Freeze drying closures for infusion bottles*

— *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*

— *Part 8: Infusion equipment for use with pressure infusion apparatus*

— *Part 9: Fluid lines for use with pressure infusion equipment*

— *Part 10: Accessories for fluid lines for use with pressure infusion equipment*

— *Part 11: Infusion filters for use with pressure infusion equipment*

— *Part 12: Check valves*

Introduction

Infusion bottles are suitable primary packaging materials for the storage of infusion solutions until they are administered to the patient. Due to the direct contact between infusion solution and the primary container components and in view of the extended storage periods, it is essential to avoid possible interactions in order to guarantee the patient's safety. Adequate means to achieve this goal include the proper selection of the primary packaging materials, the choice of suitable package design and the availability of specific criteria and methods for testing of individual container systems.