

Medical infusion equipment - Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process (ISO 15759:2005, IDT)

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- ISO 15759:2005, IDT

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# ISO 15759

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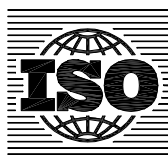
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## Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process

*Matériel de perfusion à usage médical — Capsules plastiques avec un joint à base d'élastomère pour récipients produits par le procédé d'extrusion/soufflage/remplissage (ESR)*



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ISO 15759:2005(E)

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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.

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ISO 15759 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 15759:2002), which has been technically revised.

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## Introduction

The materials used to manufacture blow-fill-seal (BFS) containers are primary packaging materials suitable for storing infusion solutions until they are administered. This International Standard deals with plastics caps with inserted elastomeric liners for use with blow-fill-seal containers and describes their dimensional and functional requirements. This International Standard takes into account that the cap is not a primary packaging component.

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# Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow–fill–seal (BFS) process

## 1 Scope

This International Standard specifies the dimensional and functional requirements for plastics caps with inserted elastomeric liners, attached to the infusion container (BFS container) by welding or by collar technique. These caps are intended for use in the packaging and handling of liquid drugs for parenteral delivery.

## 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 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*

ISO 2230, *Rubber products — Guidelines for storage*

ISO 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

ISO 3302-1, *Rubber — Tolerances for products — Part 1: Dimensional tolerances*

ISO 7500-1, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Verification and calibration of the force-measuring system*

ISO 7864, *Sterile hypodermic needles for single use*

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

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