INTERNATIONAL STANDARD

ISO 15759

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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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Contents

Page

Foreword ... iv

Introduction ... v

1 Scope ... 1

2 Normative references ... 1

3 Dimensions and designation ... 2
3.1 Plastics cap for attachment by welding technique (Form A) ... 2
3.2 Plastics cap for attachment by collar technique (Form B) ... 3
3.3 Elastomeric liner ... 4

4 Materials for cap and liner ... 4

5 Plastics cap — Physical requirements and testing ... 5
5.1 Leak-resistance test ... 5
5.2 Opening force ... 5

6 Liner — Physical requirements and testing ... 5
6.1 General requirements ... 5
6.2 Hardness ... 5
6.3 Fragmentation (coring) ... 5
6.4 Penetration force ... 5
6.5 Dynamic spike-retention capability ... 5
6.6 Static spike-retention capability of the liner and leak resistance of the piercing area ... 5
6.7 Resealability ... 5

7 Plastics cap — Chemical requirements and testing ... 5

8 Liner — Chemical requirements and testing ... 6

9 Biological requirements for plastics cap and liner ... 6

10 Packaging ... 6

11 Storage ... 6

12 Marking ... 6

Annex A (normative) **Leak-resistance test** ... 7

Annex B (normative) **Opening force needed to expose the piercing area** ... 8

Annex C (normative) **Fragmentation (coring)** ... 9

Annex D (normative) **Penetration force** ... 10

Annex E (normative) **Dynamic spike retention capability** ... 12

Annex F (normative) **Static spike-retention capability of the liner and leak resistance of the piercing area** ... 13

Annex G (normative) **Resealability** ... 14

Annex H (normative) **Holding device for elastomeric liner** ... 15

Annex I (normative) **Reference spike** ... 16

Bibliography ... 17

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 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.

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.

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*

3 Dimensions and designation

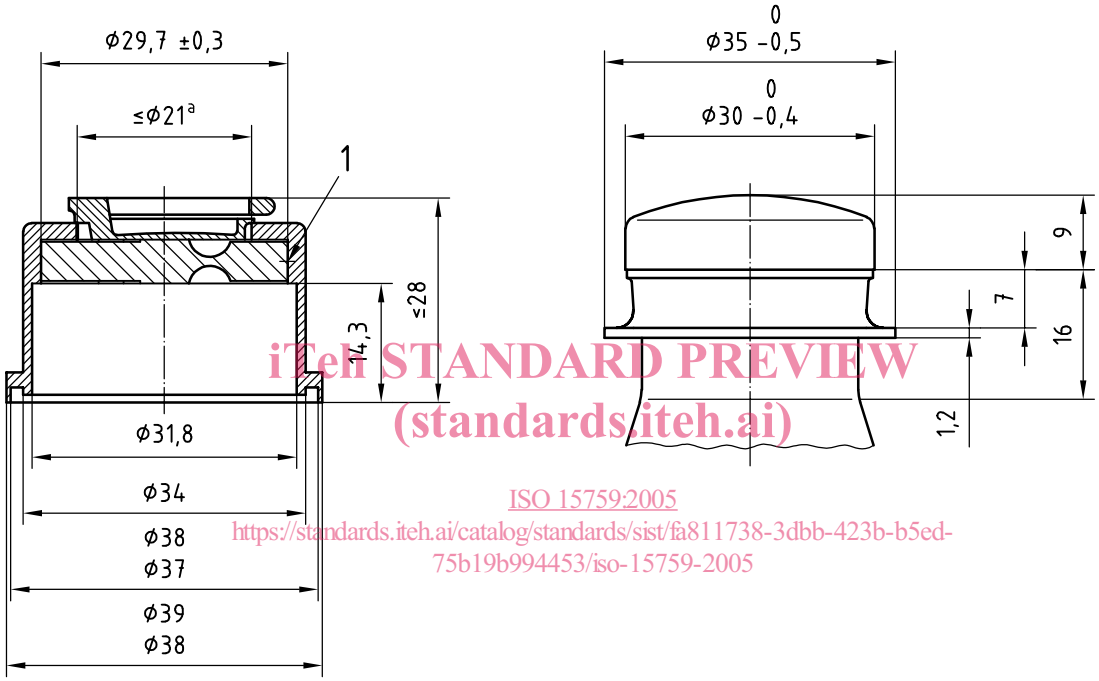
3.1 Plastics cap for attachment by welding technique (Form A)

General tolerances for Form A plastics caps shall be in accordance with ISO 2768-1; dimensions shall be in accordance with Figure 1. Elastomeric liners for such caps shall be in accordance with ISO 3302-1.

Plastics cap(s) of Form A in accordance with this International Standard shall be designated as follows:

Cap ISO 15759-BFS-A

Dimensions in millimetres



Key

1 measuring point at the centre

a Diameter of score line.

Figure 1 — Dimensions for Form A plastics caps

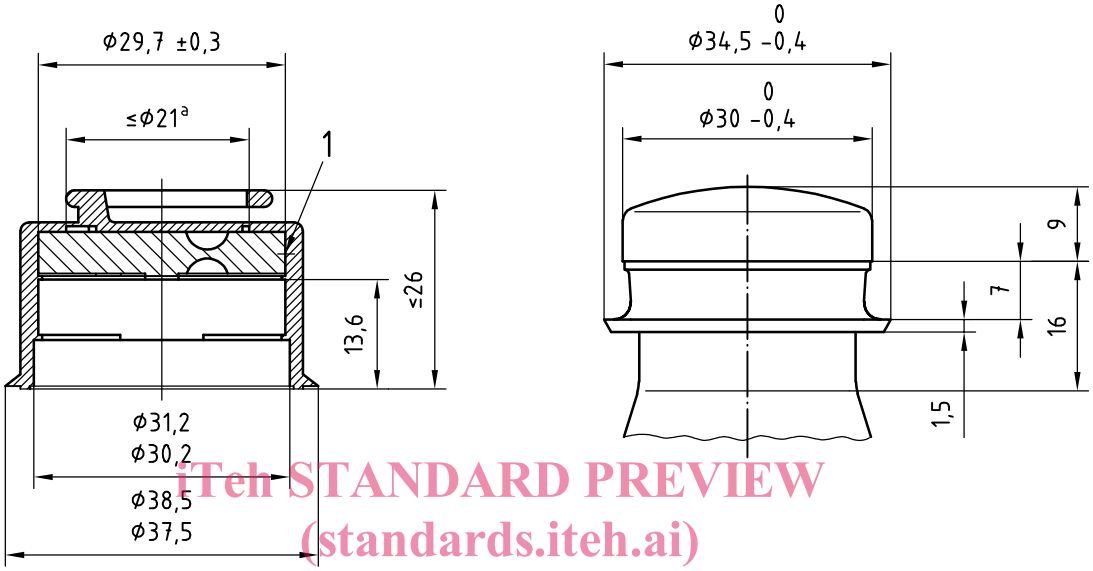
3.2 Plastics cap for attachment by collar technique (Form B)

Dimensions for Form B plastics caps shall be in accordance with Figure 2.

Plastics cap(s) of Form B in accordance with this International Standard shall be designated as follows:

Cap ISO 15759-BFS-B

Dimensions in millimetres



Key

1 measuring point at the centre

a Diameter of score line.

Figure 2 — Dimensions for Form B plastics caps

3.3 Elastomeric liner

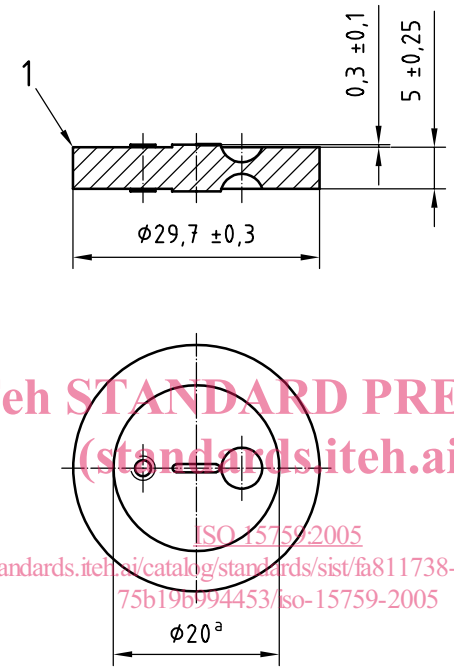
Dimensions for elastomeric liners for plastics caps of Form A or Form B shall be in accordance with Figure 3.

Elastomeric liners in accordance with this International Standard shall be designated as follows:

Elastomeric liner ISO 15759

Figure 3 illustrates a typical liner design. Other liner designs are permitted.

Dimensions in millimetres



Key

1 trimming edge max. ∅ 30,2

a Target area.

Figure 3 — Dimensions for elastomeric liners for plastics caps of Form A or Form B

4 Materials for cap and liner

4.1 Materials shall be in accordance with the requirements in Clauses 6, 7, 8 and 9. The choice of plastics and elastomeric materials shall be subject to agreement between manufacturer and customer.

4.2 Resistance to ageing depends largely on pre-sterilization techniques, storage and handling conditions. The period during which cap and liner shall comply with the requirements of this International Standard is subject to agreement between manufacturer and customer.

4.3 Compatibility of the drug with the liner shall be assessed by the user.

4.4 ISO 2230 describes storage guidelines for vulcanized elastomeric parts.

5 Plastics cap — Physical requirements and testing

5.1 Leak-resistance test

When performing the leak-resistance test of the covered piercing area in accordance with Annex A, no leakage shall be observed.

5.2 Opening force

When testing the opening force needed to expose the piercing area in accordance with Annex B, the required force shall not exceed 80 N and shall not tear the cap outside the piercing area.

6 Liner — Physical requirements and testing

6.1 General requirements

6.1.1 Injection gates and sprues are not allowed in the sealing area, i.e. between cap and liner.

6.1.2 Marks, indentations and spacers are allowed. The height of spacers shall not exceed 0,3 mm.

6.2 Hardness

Hardness requirements shall be agreed between manufacturer and customer. The hardness shall not differ from the nominal value by more than when ± 5 IRHD tested in accordance with ISO 48.

6.3 Fragmentation (coring)

When testing for fragmentation in accordance with Annex C, no more than seven fragments of diameter equal to or greater than 50 µm shall be observed per ten piercings.

6.4 Penetration force

When testing for penetration in accordance with Annex D, the force required to penetrate the liner shall not exceed 80 N. The average value shall not exceed 75 N.

6.5 Dynamic spike-retention capability

When tested in accordance with Annex E, the measured retention force shall not fall below 15 N.

6.6 Static spike-retention capability of the liner and leak resistance of the piercing area

When tested in accordance with Annex F, no leakage shall be observed between the spike and liner during a period of 4 h and the spike shall not fall out.

6.7 Resealability

When performing the test in accordance with Annex G, no air shall escape.

7 Plastics cap — Chemical requirements and testing

The plastics material used to manufacture the cap shall be physiologically harmless.