BS ISO 24166-3:2022

BSI Standards Publication

Snap-on bottles for metering pumps

Part 3: Plastic

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Part 3: Plastic

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

A list of all parts in the ISO 24166 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

This document is part of a series of International Standards for containers made from different materials used in combination with metering pumps for medicinal applications.

Glass containers are mainly used for that purpose. Plastic containers can be used as an alternative.

This document can be used for the development of standardized filling and assembling equipment.

Based on the dimensions of the containers, appropriate components, such as metering pumps and other closure systems can be developed and standardized. As such this document provides important inputs for developing entire packaging systems for medicinal applications.

Primary packaging materials are an integral part of medicinal products. Thus, depending on the jurisdiction, the principles of the current Good Manufacturing Practices (cGMP) can apply to the manufacturing of these components (e.g. ISO 15378).

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Snap-on bottles for metering pumps —

Part 3:
Plastic

1 Scope

This document specifies the shape, dimensions, fill capacities and performance requirements of plastic bottles for metering pumps. It also specifies the material for the manufacturing of such containers as well as the secondary packaging.

The document provides requirements for packaging of the plastic bottles and addresses nonsterile, ready to sterilize or sterile as three possible options.

This document is applicable to colourless or coloured containers moulded from plastic and intended to be used in the packaging, storage or transportation of products intended for medicinal use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
base foil
packaging component for protection of the pallet load from contamination

3.2
bottle
vial
container made of a suitable material, which is intended for packaging, storage and application of liquid medicinal products

EXAMPLE Tubular glass, moulded glass or plastic.

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