Sterile single-use syringes, with or without needle, for insulin

Seringues à insuline, stériles, non réutilisables, avec ou sans aiguille
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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO’s adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 84, Devices for administration of medicinal products and catheters.

This third edition cancels and replaces the second edition (ISO 8537:2007), which has been technically revised to include the following changes:

a) revised the introduction;

b) revised the scope to include various concentrations of insulin, specified plastic materials and excluded, e.g. single-use syringes made of glass;

c) added some normative references;

d) added new definitions;

e) added new colour codes for higher concentration of insulin;

f) clarified the drawing to illustrate the component of the syringe;

g) included general requirements;

h) revised test methods for syringes;

i) revised the labelling requirement;

j) moved the syringe sizes and graduated scales in Annex H;

k) deleted Annex I.
Introduction

This International Standard covers insulin syringes primarily intended for human use and provides performance and testing requirements. It permits broader variation in design so as to not limit innovation in technology or methods of packaging. Its appearance and layout are consistent with other TC 84 International Standards, which are designed to be more performance-based than design-prescriptive.

Manufacturers are expected to follow a risk-based approach and employ usability engineering during the design, development and manufacture of insulin syringes.

This edition introduces general requirements as design guidelines for manufacturers. This edition retains a number of limits on requirements, which were originally based on consensus opinion but subsequently have been confirmed in practice.

This International Standard does not specify materials to be used for the construction and lubrication of sterile insulin syringes and needles for single use because their selection will depend, to some extent, upon the manufacturer’s specific syringe design, process of manufacture, and sterilization method.

Insulin syringes and needles are to be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices.

This International Standard emphasizes the importance of having individual syringes that are appropriately graduated and labelled for only one concentration of insulin. Serious problems can result if a syringe is used with a concentration of insulin that is different from the one for which it was designed. Hazards associated with dosing errors with highly concentrated insulin (U300 and U500) are considered higher than the experience with U40 and U100.

It is preferred that when more than one insulin concentration is in a market, the new concentration be provided in a dedicated delivery system that make miss-dosing less likely.

In acknowledgement that insulin in higher concentrations in vials are available in some markets, new formulations are under development and dedicated delivery systems other than syringes are not always appropriate for all markets, this International Standard introduces new colour codes to differentiate syringes for the new higher concentrations of insulin.

The sampling plans for inspection selected for this International Standard are intended to verify the design at a high confidence level. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality systems, for example, the ISO 9000 series and ISO 13485.

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244, developed by ISO/TC 84.