# SYNOPSIS

**Doc : MHD 12 (10630) IS 12227 : 2016 /ISO 8537 : 2016 - Sterile Single-Use Syringes, With Or Without Needle, For Insulin (Second Revision)**

**Scope:**

This standard specifies requirements and test methods for empty, sterile, single-use syringes, with or without needles, made of plastic materials and intended solely for the injection of insulin, with which the syringes are filled by the end user. This International Standard covers syringes intended for single-use only in humans and with insulins of various concentrations.

The insulin syringes specified in this International Standard are intended for use (i.e. insulin injection) immediately after filling and are not intended to contain insulin for extended periods of time.

ISO 8537:2016 excludes single-use syringes made of glass, syringes for use with power-driven syringe pumps, syringes that are pre-filled by the manufacturer, and syringes intended to be stored after filling (e.g. in a kit intended for filling by a pharmacist).

**a) Salient features of content:**

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

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

This 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 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. This standard introduces new colour codes to differentiate syringes for the new higher concentrations of insulin.

**c) Type/grades/classes, if any covered in the standard**: Nil.

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