SOL-MILLENNIUM®

Technical Data Sheet

Product specification

1. Product name	SOL-M™ Slip Tip Insulin Syringe without Needle
2. Description	The SOL-M™ Slip Tip Insulin Syringe without Needle is used to inject insulin into the body.
3. Characteristics	SOL-M™ Slip Tip Insulin Syringe without Needle is sterilized by Ethylene Oxide Gas. Each Blister Pack, Dispenser Box and Case are labeled with the contents and the appropriate information per the FDA's Quality System Regulation and Labeling requirements.
4. Intended use	The Insulin Syringe is used to inject insulin into the body.
5. Instructions for use	N/A
6. Sizes and REF numbers	

REF	Size
161000	1ml

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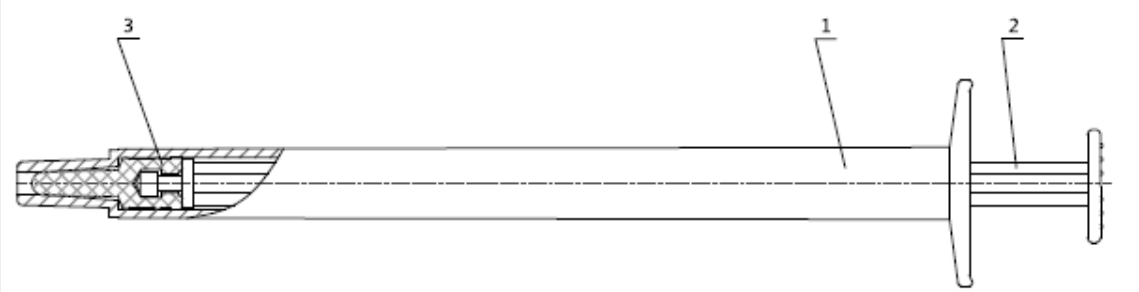
Technical information

1. List of Materials	Component name			Material
	Gasket			Latex free rubber
	Barrel			PP: 5250T
	Plunger			PP: 5250T
	Barrel Lubricant			Silicon oil: DC 360 12500cst
2. Latex free	YES			
3. PHT / DEHP / PVC / BPA free	YES			
4. Shelf life	5 years			
5. Sterilization method	Sterilized using Ethylene Oxide			
6. Packaging specification	6.1 Sales unit	1 ml	100	Units per box
		1 ml	800	Units per case
7. Technical Drawing				

1. Barrel
2. Plunger
3. Gasket

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Quality and Regulatory information

1. Quality certificate	Quality Management System according ISO 13485
2. Product classification	Class Is+m according to Annex IX of MDD 93/42/EEC

3. List of standards

The product is compliant with the following standards and regulations:

Document reference	Title
ISO 8537:2016	Sterile single-use syringes, with or without needle, for insulin
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-4:2017	Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
ISO 10993-7:2008/Cor 1:2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
ISO 11607-1:2019	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11737-2:2009	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 11135-1:2014/Amd 1:2018	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

REV	03	Date	12.07.2019