

Technical Data Sheet



Product specification

1. Product name	SOL-M™ Slip Tip Insulin Syringe without Needle	
2. Description	SOL-M™ Slip Tip Insulin Syringe without Needle is a sterile, single use insulin syringe, used to inject insulin into the body.	
3. Intended use	The Insulin Syringe is used to inject insulin into the body.	
4. Instructions for Use	N/A	
5. Sizes and REF numbers	REF	Product Description
	161000	SOL-M 1ml Insulin Syringe Slip Tip w/o Needle (U-100 Insulin Only)

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
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3. PHT /DEHP /PVC /BPA free	YES
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4. Shelf life	5 years
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5. Sterilization method	Ethylene oxide (EO)
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6. Packaging specification	6.1 Sales unit	100	Units per box
		800	Units per case

7. Technical Drawing		
	<ol style="list-style-type: none"> 1. Plunger 2. Barrel 3. Gasket 	

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	

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EN 1041:2008+A1:2013

Information supplied by the manufacturer of medical devices

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Date

29.04.2021