SOL-MILLENNIUM®

Technical Data Sheet

Product specification

1. Product name	SOL-M™ Slip Tip Syringe without Needle
2. Description	SOL-M™ Slip Tip Syringe without Needles are used to inject medicines and vaccines into, or withdraw fluids from, the body.
3. Characteristics	SOL-M™ Slip Tip Syringe without Needles are 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. High barrel transparency – for good visualization of syringe content Black graduation – for ideal contrast and readability Safe plunger backstop – reduced sliding force Compatible with standard connectors Not containing any rubber material
4. Intended use	SOL-M™ Slip Tip Syringe without Needles are used in human skin, muscle and intravenous injection or liquid extraction under normal operation.
5. Instructions for use	N/A
6. Sizes and REF numbers	

REF	Size
P180011	1 ml
P180011LDS	1 ml
P180003ST	3 ml
P180005ST	5 ml
P180010ST	10 ml
P180010ET	10 ml
P180020ST	20 ml
P180020ET	20 ml
P180060ET	60 ml

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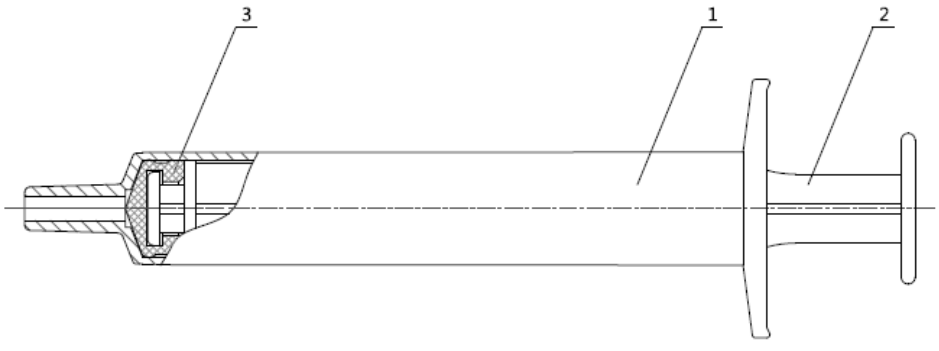
Technical information

1. List of Materials	Component name	Material	
	Plunger	PP	
	Barrel	PP	
	Gasket	Isoprene rubber	
	Barrel Lubricant	Silicon oil	
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	1ml\3ml\5ml \10ml\20ml 100 60ml 30	Units per box
		1ml\3ml\5ml\20ml 800	Units per case
		10ml 1200	
		60ml 240	
	6.2 Storage and transportation Sterilized product should be stored under dry, clean and adequately ventilated conditions. The product should be protected.		
7. Technical Drawing			

1. Plunger
2. Barrel
3. Gasket

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Quality and Regulatory information

1. Quality certificate	Quality Management System according to ISO 13485
2. Product classification	Class Ⅱa 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 7886-1:2017	Sterile hypodermic syringes for single use-Part 1: Syringes for manual use
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
ISO10993-4:2017	Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
ISO10993-5: 2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
ISO10993-7:2008/Cor 1:2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
ISO10993-10: 2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
ISO10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
ISO 10993-12:2012	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling 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 validation of a sterilization process
ISO 11135:2014/Amd 1:2018	Sterilization of health-care products -- Ethylene oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 14971:2007	Medical Devices – Application of Risk Management to

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		Medical Devices
	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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