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.
4. Intended use	SOL-M™ Slip Tip Syringe without Needles are used to inject medicine or vaccines into, or withdraw fluids from, the body.
5. Instructions for use	N/A
6. Sizes and REF numbers	

REF	Size
180011	1ml
180003ST	3ml
180005ST	5ml
180010ST	10ml
180020ST	20ml
180030ST	30ml
180050ST	50ml

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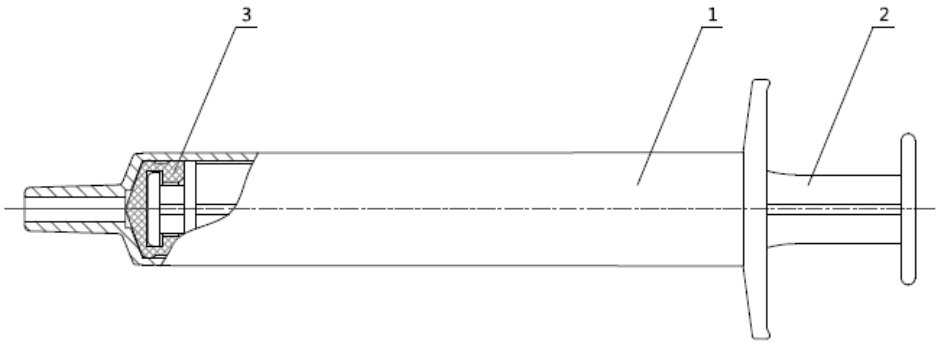
Technical information

1. List of Materials	Component name	Material
	Plunger	PP: 5250T
	Barrel	PP: 5250T
	Gasket	Latex free rubber
	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	1ml\3ml\5ml \10ml\20ml 30ml 50ml	100 50 30	Units per box
		1ml\3ml\5ml	800	Units per case
		10ml	1200	
		20ml	800	
		30ml	400	
		50ml	240	

7. Technical Drawing



1. Plunger
2. Barrel
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 7886-1:1993/Cor 1:1995	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 10993-1:2009/Cor 1:2010	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	ISO10993-4:2002/Amd 1:2006	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
	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 11607-1:2006/Amd 1:2014	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
	ISO 11607-2:2006/Amd 1:2014	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
	EN980:2008	Symbols for use in the labelling of medical devices
	EN1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

REV	01	Date	30.01.2017