SOL-MILLENNIUM®

Technical Data Sheet

Product specification

1. Product name	SOL-M™ Eccentric Tip Syringe No Needle
2. Description	SOL-M™ Eccentric Tip Syringe No Needles are used to inject medicines and vaccines into, or withdraw fluids from, the body.
3. Characteristics	SOL-M™ Eccentric Tip Syringe No 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™ Eccentric Tip Syringe No 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
180010ET	10ml
180020ET	20ml
180030ET	30ml
180060ET	60ml

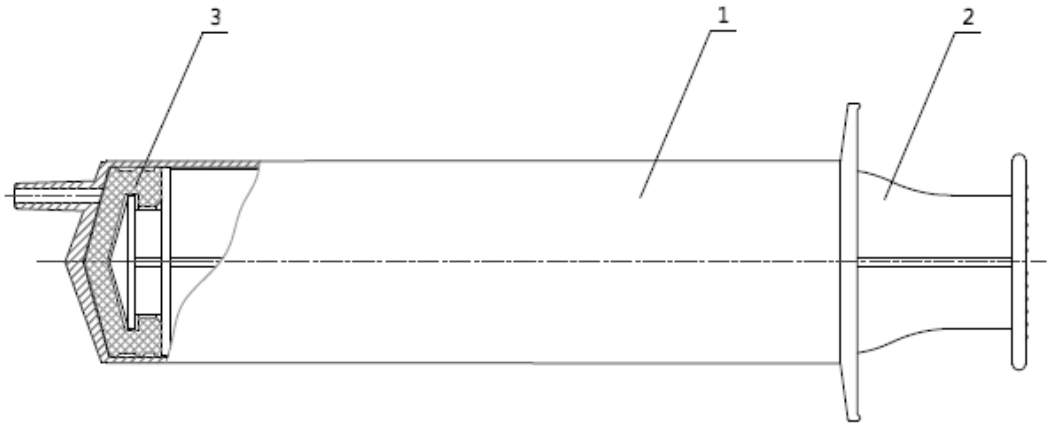
SOL-MILLENNIUM®

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	10ml\20ml 60ml	100 30	Units per box
		10ml	1200	Units per case
		20ml	800	
		60ml	240	

7. Technical Drawing



1. Barrel
2. Plunger
3. Gasket

SOL-MILLENNIUM®

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 validation of a sterilization process
EN 980:2008	Symbols for use in the labelling of medical devices

REV	02	Date	03.01.2017