SOL-MILLENNIUM®

Technical Data Sheet

Product specification

1. Product name	SOL-M™ Luer Adapter
2. Description	SOL-M™ Luer Adapter has a Luer connection, and a non-patient needle covered with a rubber sleeve.
3. Intended use	SOL-M™ Luer Adapter is intended to be used as component for sampling collection with devices.
4. Sizes and REF numbers	

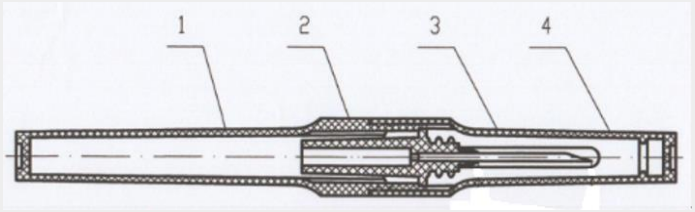
REF	Description
LA21920	SOL-M™ Luer Adapter

Technical information

1. List of materials	Component name	Material	
	Needle cap	Polypropylene	
	Tube needle cap	Polypropylene	
	Male luer lock adapter	Polypropylene	
	Rubber cap	Isoprene Rubber	
	Non-patient needle	Stainless steel SUS304	
	Adhesive	Epoxy glue	
	Lubricant	Silicon oil	
2. Latex free	YES		
3. PHT / DEHP / PVC free	YES		
4. Shelf Life	5 years		
5. Sterilization method	Sterilized using Ethylene Oxide		
6. Packaging specification	6.1 Sales unit	100	Units per box
		1000	Units per case

7. Technical Drawing

Luer Adapter



1. Tube needle cap 2. Male luer lock adapter and non-patient needle 3. Rubber cap 4. Needle cap

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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 9626:2016	Stainless steel needle tubing for the manufacture of medical devices
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% taper for intravascular or hypodermic applications
EN 1041:2008+A1:2013	Information Supplied by the Manufacturer with Medical Devices
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 780:2015	Packaging. Distribution packaging. Graphical symbols for handling and storage of packages
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 10993-10:2010	Biological evaluation of medical devices — Part 10：Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

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