Kindly Enterprise Development Group Co., Ltd

Technical Data Sheet

Product specification

1. Product name	SOL-M™ Multi-Sample Needle
2. Intended use	SOL-M™ Multi-Sample Needle is used in routine blood collection from a patient into evacuated blood collection tubes and is exclusively single-use.
3. Indications for use	SOL-M™ Multi-Sample Needle is used in routine blood collection from a patient into evacuated blood collection tubes and is exclusively single-use.
4. Instructions for use	N/A
5. Sizes and REF numbers	

REF	Size
110201020001	23G*1”
110201020002	22G*1”
110201020003	22G*1 1/2”
110201020004	21G*1”
110201020005	21G*1 1/2”
110201020006	20G*1”
110201020007	20G*1 1/2”
110201020008	18GX1”
110201020009	18GX1 1/2”

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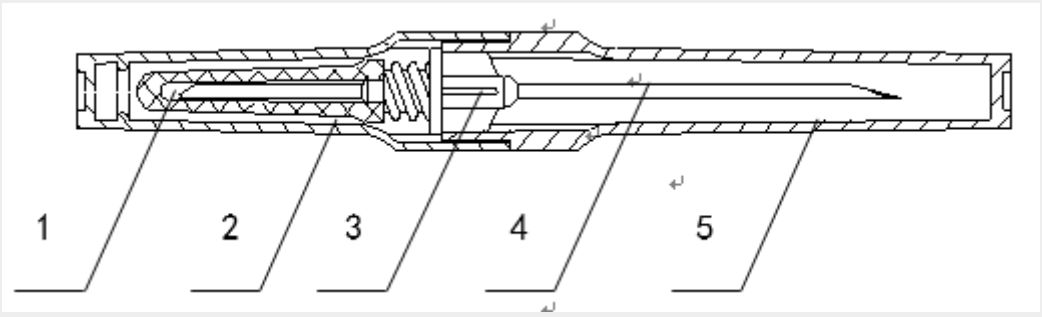
Technical information

1. List of Materials	**Component name**	**Material**
	Rubber sleeve	Isoprene Rubber
	Protective cap (S)	PE: 2911
	Needle hub	ABS: GP 22
	Needle tube	Stainless steel: SUS304
	Protective cap (L)	PP: 5450XT
	Adhesive	Epoxy: YD-128
	Needle Lubricant	Silicon oil: Xilikang 201-350cst
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	100	Units per box
		1000	Units per case

7. Technical Drawing



1. Rubber sleeve
2. Protective cap(S)
3. Needle hub
4. Needle tube
5. Protective cap(L)

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Quality and Regulatory information

1. Quality certificate	Quality Management System according 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 7864:2016	Sterile hypodermic needles for single use -- Requirements and test methods
ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods
ISO 10993-1:2009/Cor 1:2010	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
ISO10993-11:2006	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part1: General requirements
ISO 15223-2: 2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
ISO 6009:2016	Hypodermic needles for single use - Colour coding for identification
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 11138-1:2017	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 11135:2014	Sterilization of health care products -- Ethylene oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11737-1: 2006/Cor 1:2007	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on product
ISO 11737-2: 2009	Sterilization of medical devices - Microbiological methods -Part 2: Tests of sterility performed in the validation of a sterilization process

REV	02	Date	29.03.2018