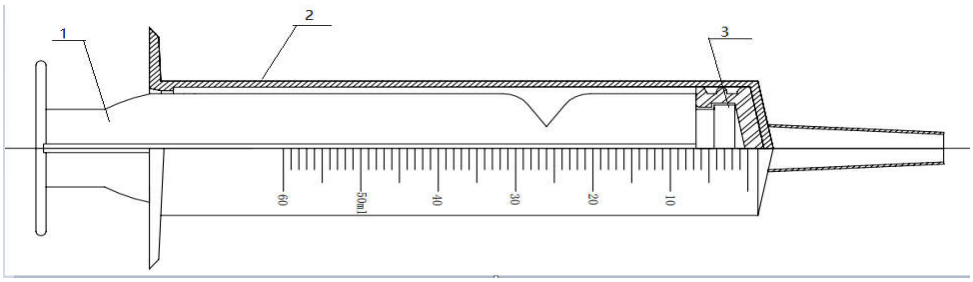
Tecnnical Data Sheet

1. Product Name	Syringes	
2. Description	50ml	
3. Characteristics	without needle, with	
4. Intended use	This Syringes are used for intradermal, subcutaneous, intramuscular, intravenous injection or extraction of liquid(blood).	
5. Instructions for use	See IFU	
6. Sizes & REF numbers	REF NO.	Product Descirption
	50ml	Catheter tip
Technical Information	Component Name	Material
1. List of materials	1. Core Bar	PP
	2. Barrel	PP
	3. Piston	Natural latex/ Natual latex-free
2. Latex free	Piston can be natural latex piston or natural latex-free	
3. PHT/DEHP free	Yes	
4. Shelf life	3 years	
5. Sterilization method	Sterilized using Ethylene Oxide	
6. Packaging specification	6.1 Sales Unit	
	50ml	Single blister package, 25pcs/box,300pcs/ctn
7. Technical Drawing		

Quality & Regulatory Information

1. Quality certificate	Quality Management Syestem according to ISO13485	
2. Product Classification	Class I in sterile condition accoridng to Annex V of MDD 93/42ECC	
	The product is compliant with the following standards and regulations:	
	Document reference	Titile
	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
	EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
	EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)

3. List of Standards	**EN ISO 10993-11:2018**	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
	EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
	EN ISO 11607-1:2020/prA1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems - Amendment 1 (ISO 11607-1:2019/DAM 1:2022)
	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
	EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO
	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-
	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
REV	**02**	**Date: 2023/09/14**

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