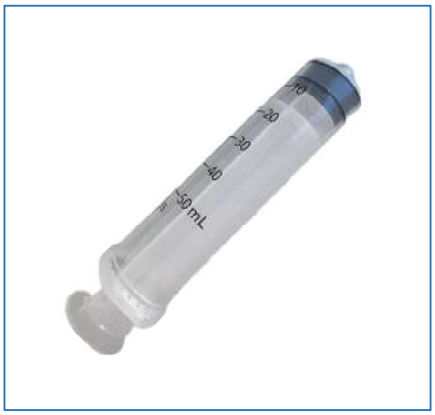
TECHNICAL DATA SHEET

Syringe



Intended use:

This Syringes are used for intradermal, subcutaneous, intramuscular, intravenous injection or extraction of liquid(blood).

Instruction for use see IFU.

Product range

REF	Description
50ml	Luer lock, with core bar fit for syringe pump, Retaining ring to help prevent accidental plunger pullout 2-stage plunger sealing gasket that prevents leakage of solution around the plunger Graduation Volume: 50ml

Material information

Core Bar……PP

Barrel……PP

Piston……Natural latex-free

Sterilization

Sterile?.....YES

Shelf life……3 years

Certificates

Product classification…… Class I sterile

Quality system certificate……ISO 13485

Storage

No special storage or transportation condition. Recommendations to store in room temperature.

Store in dry and warm place and not exposed to strong light.

Standards

Standards	**Reference**	**Content**
ISO 7886-1	2017	Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
EN ISO 15223-1	2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Standards	Reference	Content
EN ISO 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7	2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Technical Corrigendum 1
EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
EN ISO 10993-11	2018	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation
EN ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN 17141	2020	Cleanrooms and associated controlled environments — Biocontamination control
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
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems - Amendment 1
EN ISO 11607-2	2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1	2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
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