PRODUCT TECHNICAL DATA SHEET

PROSUM^{Ò} Hypodermic Syringe without needle
Sterile, Single use, Latex free

1. GENERAL INFORMATION

1.1 General

Single use, sterile Hypodermic Syringes are intended for general purpose aspiration and injection of fluids after filling by the end-users and are not intended to contain the medicament for extended periods of time.

**Figures not to scale*

Reference	Description
SC-50-F	Irrigation Syringe Catheter Tip, Flat plunger 50ml
SC-60-F	Irrigation Syringe Catheter Tip, Flat plunger 60ml
SC-60-B	Irrigation Syringe Catheter Tip, Bulb 60ml
SC-60-R	Irrigation Syringe Catheter Tip, Ring plunger 60ml
SC-100-R	Irrigation Syringe Catheter Tip, Ring plunger 100ml
SC-30-F	Irrigation Syringe Catheter Tip, Flat plunger 30ml
SC-150-R	Irrigation Syringe Catheter Tip, Ring plunger 150ml
S0-011	Syringe without Needle Luer Slip 1ml
S0-021	Syringe without Needle Luer Slip 2ml
S0-031	Syringe without Needle Luer Slip 3ml
S0-051	Syringe without Needle Luer Slip 5ml
S0-101	Syringe without Needle Luer Slip 10ml
S0-201	Syringe without Needle Luer Slip 20ml
S0-601	Syringe without Needle Luer Slip 60ml
S0-010	Syringe without Needle Luer lock 1ml
S0-020	Syringe without Needle Luer lock 2ml
S0-030	Syringe without Needle Luer lock 3ml
S0-050	Syringe without Needle Luer lock 5ml
S0-100	Syringe without Needle Luer lock 10ml

Reference	Description
S0-200	Syringe without Needle Luer lock 20ml
S0-300	Syringe without Needle Luer lock 30ml
S0-600	Syringe without Needle Luer lock 60ml
S0-101ET	Syringe without Needle Eccentric Tip 10ml
S0-201ET	Syringe without Needle Eccentric Tip 20ml
S0-301ET	Syringe without Needle Eccentric Tip 30ml
S0-601ET	Syringe without Needle Eccentric Tip 60ml
S0-03P	Syringe without Needle Luer lock 3ml
S0-05P	Syringe without Needle Luer lock 5ml
S0-10P	Syringe without Needle Luer lock 10ml
S0-20P	Syringe without Needle Luer lock 20ml
S0-30P	Syringe without Needle Luer lock 30ml
S0-60P	Syringe without Needle Luer lock 60ml
S0-011N	Syringe without Needle Luer Slip 1ml
S0-010L	Syringe without Needle Luer lock 1ml
S0-030L	Syringe without Needle Luer lock 3ml
SPC0-010	Prosum Polycarbonate Syringe Luer lock 1ml
SPC0-030	Prosum Polycarbonate Syringe Luer lock 3ml
SPC0-050	Prosum Polycarbonate Syringe Luer lock 5ml
SPC0-100	Prosum Polycarbonate Syringe Luer lock 10ml
SPC0-200	Prosum Polycarbonate Syringe Luer lock 20ml
SPC0-300	Prosum Polycarbonate Syringe Luer lock 30ml
S0-010T	Tuberculin Syringe withou Needle 1ml Luer lock
S0-011T	Tuberculin Syringe withou Needle 1ml Luer slip

1.2 Material

Component	Material
Plunger	Polypropylene
Barrel	Polypropylene Polycarbonate (SPC0-010 only)
Piston	Isoprene rubber
Lubricant	Silicone oil

1.3 Material of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

Material	Comment
DEHP/Phthalates	The products do not contain DEHP.
Latex	The products do not contain natural latex.
Bisphenol A	The products do not contain Bisphenol A.
Polyvinyl chloride (PVC)	The products do not contain polyvinyl chloride

1.4 Biocompatibility

Comply with the requirements of the standard for biocompatibility of medical devices, ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

1.5 Sterilization

Sterilized by EO gas in accordance with EN ISO 11135:2014

1.6 Shelf life

5 years shelf life

1.7 Certification

Certification	Certificate Number	Notified Body	Certificate Holder
ISO 13485:2016	GB20/965500	SGS United Kingdom Ltd	Prosum Medical Limited Unit 14 Cowley Mill Road, Uxbridge, Greater London, UB8 2DB, United Kingdom
MDD 93/42/EEC	SGS NB 1639, GB20/965681	SGS Belgium NV Notified Body 1639	Prosum Medical Limited Unit 14 Cowley Mill Road, Uxbridge, Greater London, UB8 2DB, United Kingdom
UKCA UK MDR 2002	GB23/00000146	SGS United Kingdom Ltd Approved Body 0120	Prosum Medical Limited Unit 14 Cowley Mill Road, Uxbridge, Greater London, UB8 2DB, United Kingdom

1.8 Standards

Regulations/Standards	Description
ISO 7886-1:2017	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
ISO 7886-2:2020	Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps
ISO 6009:2016	Hypodermic needles for single use - Colour coding for identification.
MEDDEV.2.7.1 Rev.4	Guidelines on medical devices
EN 556-1:2001/ AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN 1041:2008+A1:2013	Information Supplied by the Manufacturer with Medical Devices
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications -Part 7: Connectors for intravascular or hypodermic applications
EN ISO 11135:2014	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on product
EN ISO 11737-2:2020	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11138-1:2017	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 13485:2016	Medical Devices – Quality management system – Requirements for regulatory purposes
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods
EN ISO 14698-2:2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 2: Evaluation & Interpretation of Biocontamination Data
EN ISO 14644-1:2015	Cleanrooms and Associated Controlled Environments Part 1: Classification and Air Cleanliness
EN ISO 14644-2:2015	Cleanrooms and Associated Controlled Environments Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments —Part 3: Test methods
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 80369-7:2017	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

Regulations/Standards	Description
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
EN ISO10993-5:2009	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
EN ISO10993-10:2013	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO10993-11:2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
ASTM F1980:2016	Standard guide for accelerated aging of sterile barrier systems for medical device

1.9 Classification

Irrigation and General-purpose Syringes are Class I Sterile Medical Devices under Rule 1, Annex IX of Medical Devices Directive 93/42/EEC and Part II of UK Medical Devices Regulations 2002, Annex V.

Syringes for use with pump are Class IIa Sterile Medical Devices under Rule 2, Annex IX of Medical Devices Directive 93/42/EEC and Part II of UK Medical Devices Regulations 2002, Annex V.

2. CAUTION

Re-use of single use devices creates a potential risk for patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

3. STORAGE CONDITIONS

Store in a dry environment and keep away from sunlight.

4. Labelling

In accordance to European Medical Device directive.

Symbols	Description
	Do not re-use
	Catalogue Number
	Batch code / Lot number
	Date of Manufacture
	Use-by-date
	Manufacturer
	Caution
	Latex free
	Keep away from sunlight
	Keep dry
	Sterilized using ethylene oxide
	Do not use if package is damaged
	EC Representative
	Unique device identifier
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Medical device

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