

PRODUCT TECHNICAL DATA SHEET

Prosum[®] Hypodermic Needle and Prosum[®] ProSafe[®] Safety Hypodermic Needle
Sterile, Single use, Latex free

1. GENERAL INFORMATION

1.1 General

Sterile single-use hypodermic needles are intended to use with syringe for withdraw, inject and general hypodermic administration of medicine. The safety hypodermic needles can help preventing needlestick injuries (NSIs).



Figure.1 Hypodermic Needle

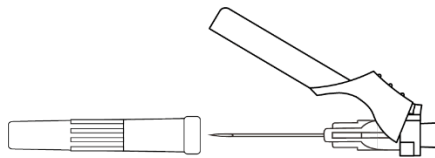


Figure.2 Safety Hypodermic Needle

REF	Description
N300500	Prosum Hypodermic Needle 30G × 1/2" (0.3 × 13mm) Yellow
N290500	Prosum Hypodermic Needle 29G × 1/2" (0.33 × 13mm) Red
N271500	Prosum Hypodermic Needle 27G × 1 1/2" (0.4 × 38mm) Grey
N270340	Prosum Hypodermic Needle 27G × 3/4" (0.4 × 19mm) Grey
N270500	Prosum Hypodermic Needle 27G × 1/2" (0.4 × 13mm) Grey
N260580	Prosum Hypodermic Needle 26G × 5/8" (0.45 × 16mm) Brown
N260500	Prosum Hypodermic Needle 26G × 1/2" (0.45 × 13mm) Brown
N260380	Prosum Hypodermic Needle 26G × 3/8" (0.45 × 10mm) Brown
N252001	Prosum Hypodermic Needle 25G × 2" (0.5 × 50mm) Orange
N251501	Prosum Hypodermic Needle 25G × 1 1/2" (0.5 × 38mm) Orange
N251001	Prosum Hypodermic Needle 25G × 1" (0.5 × 25mm) Orange
N250581	Prosum Hypodermic Needle 25G × 5/8" (0.5 × 16mm) Orange
N250501	Prosum Hypodermic Needle 25G × 1/2" (0.5 × 13mm) Orange
N241001	Prosum Hypodermic Needle 24G × 1" (0.55 × 25mm) purple
N232001	Prosum Hypodermic Needle 23G × 2" (0.6 × 50mm) Blue
N231501	Prosum Hypodermic Needle 23G × 1 1/2" (0.6 × 38mm) Blue
N231251	Prosum Hypodermic Needle 23G × 1 1/4" (0.6 × 32mm) Blue
N231001	Prosum Hypodermic Needle 23G × 1" (0.6 × 25mm) Blue
N230581	Prosum Hypodermic Needle 23G × 5/8" (0.6 × 16mm) Blue
N230341	Prosum Hypodermic Needle 23G × 3/4" (0.6 × 19mm) Blue
N222001	Prosum Hypodermic Needle 22G × 2" (0.7 × 50mm) Black
N221501	Prosum Hypodermic Needle 22G × 1 1/2" (0.7 × 38mm) Black

REF	Description
N221251	Prosum Hypodermic Needle 22G × 1 1/4" (0.7 × 32mm) Black
N221001	Prosum Hypodermic Needle 22G × 1" (0.7 × 25mm) Black
N220581	Prosum Hypodermic Needle 22G × 5/8" (0.7 × 16mm) Black
N212001	Prosum Hypodermic Needle 21G × 2" (0.8 × 50mm) Green
N211501	Prosum Hypodermic Needle 21G × 1 1/2" (0.8 × 38mm) Green
N211001	Prosum Hypodermic Needle 21G × 1" (0.8 × 25mm) Green
N201501	Prosum Hypodermic Needle 20G × 1 1/2" (0.9 × 38mm) Yellow
N201001	Prosum Hypodermic Needle 20G × 1" (0.9 × 25mm) Yellow
N191501	Prosum Hypodermic Needle 19G × 1 1/2" (1.1 × 38mm) Cream
N191001	Prosum Hypodermic Needle 19G × 1" (1.1 × 25mm) Cream
N182001	Prosum Hypodermic Needle 18G × 2" (1.2 × 50mm) Pink
N181501	Prosum Hypodermic Needle 18G × 1 1/2" (1.2 × 38mm) Pink
N181001	Prosum Hypodermic Needle 18G × 1" (1.2 × 25mm) Pink
N161501	Prosum Hypodermic Needle 16G × 1 1/2" (1.6 × 38mm) White
N162001	Prosum Hypodermic Needle 16G × 2" (1.6 × 50mm) White
N141501	Prosum Hypodermic Needle 14G × 1 1/2" (2.1 × 38mm) Pale Green
N142001	Prosum Hypodermic Needle 14G × 2" (2.1 × 50mm) Pale Green
100/box, 5000/case	
N300500-S	Prosum ProSafe Safety Hypodermic Needle 30G × 1/2" (0.3 × 13mm) Yellow
N290500-S	Prosum ProSafe Safety Hypodermic Needle 29G × 1/2" (0.33 × 13mm) Red
N271500-S	Prosum ProSafe Safety Hypodermic Needle 27G × 1 1/2" (0.4 × 38mm) Grey
N270340-S	Prosum ProSafe Safety Hypodermic Needle 27G × 3/4" (0.4 × 19mm) Grey
N270500-S	Prosum ProSafe Safety Hypodermic Needle 27G × 1/2" (0.4 × 13mm) Grey
N260580-S	Prosum ProSafe Safety Hypodermic Needle 26G × 5/8" (0.45 × 16mm) Brown
N260500-S	Prosum ProSafe Safety Hypodermic Needle 26G × 1/2" (0.45 × 13mm) Brown
N260380-S	Prosum ProSafe Safety Hypodermic Needle 26G × 3/8" (0.45 × 10mm) Brown
N251501-S	Prosum ProSafe Safety Hypodermic Needle 25G × 1 1/2" (0.5 × 38mm) Orange
N251001-S	Prosum ProSafe Safety Hypodermic Needle 25G × 1" (0.5 × 25mm) Orange
N250581-S	Prosum ProSafe Safety Hypodermic Needle 25G × 5/8" (0.5 × 16mm) Orange
N241001-S	Prosum ProSafe Safety Hypodermic Needle 24G × 1" (0.55 × 25mm) purple
N231501-S	Prosum ProSafe Safety Hypodermic Needle 23G × 1 1/2" (0.6 × 38mm) Blue
N231251-S	Prosum ProSafe Safety Hypodermic Needle 23G × 1 1/4" (0.6 × 32mm) Blue
N231001-S	Prosum ProSafe Safety Hypodermic Needle 23G × 1" (0.6 × 25mm) Blue
N230341-S	Prosum ProSafe Safety Hypodermic Needle 23G × 3/4" (0.6 × 19mm) Blue
N230581-S	Prosum ProSafe Safety Hypodermic Needle 23G × 5/8" (0.6 × 16mm) Blue
N222001-S	Prosum ProSafe Safety Hypodermic Needle 22G × 2" (0.7 × 50mm) Black
N221501-S	Prosum ProSafe Safety Hypodermic Needle 22G × 1 1/2" (0.7 × 38mm) Black
N221251-S	Prosum ProSafe Safety Hypodermic Needle 22G × 1 1/4" (0.7 × 32mm) Black
N221001-S	Prosum ProSafe Safety Hypodermic Needle 22G × 1" (0.7 × 25mm) Black
N212001-S	Prosum ProSafe Safety Hypodermic Needle 21G × 2" (0.8 × 50mm) Green
N211501-S	Prosum ProSafe Safety Hypodermic Needle 21G × 1 1/2" (0.8 × 38mm) Green
N211001-S	Prosum ProSafe Safety Hypodermic Needle 21G × 1" (0.8 × 25mm) Green
N201501-S	Prosum ProSafe Safety Hypodermic Needle 20G × 1 1/2" (0.9 × 38mm) Yellow
N201001-S	Prosum ProSafe Safety Hypodermic Needle 20G × 1" (0.9 × 25mm) Yellow
N191501-S	Prosum ProSafe Safety Hypodermic Needle 19G × 1 1/2" (1.1 × 38mm) Cream
N191001-S	Prosum ProSafe Safety Hypodermic Needle 19G × 1" (1.1 × 25mm) Cream

REF	Description
N181501-S	Prosum ProSafe Safety Hypodermic Needle 18G × 1 1/2" (1.2 × 38mm) Pink
N181001-S	Prosum ProSafe Safety Hypodermic Needle 18G × 1" (1.2 × 25mm) Pink
100/box, 800/case	
N34009L	Prosum Hypodermic Needle, Low dead-space 34G × 9mm Orange
N34050L	Prosum Hypodermic Needle, Low dead-space 34G × 1/2" (0.18 × 13mm) Orange
N33009L	Prosum Hypodermic Needle, Low dead-space 33G × 9mm Black
N33050L	Prosum Hypodermic Needle, Low dead-space 33G × 1/2" (0.2 × 13mm) Black
N32050L	Prosum Hypodermic Needle, Low dead-space 32G × 1/2" (0.23 × 13mm) Deep Green
N31058L	Prosum Hypodermic Needle, Low dead-space 31G × 5/8" (0.25 × 16mm) White
N31050L	Prosum Hypodermic Needle, Low dead-space 31G × 1/2" (0.25 × 13mm) White
N31009L	Prosum Hypodermic Needle, Low dead-space 31G × 9mm White
N30050L	Prosum Hypodermic Needle, Low dead-space 30G × 1/2" (0.3 × 13mm) Yellow
N30090L	Prosum Hypodermic Needle, Low dead-space 30G × 3/8" (0.3 × 9mm) Yellow
N29050L	Prosum Hypodermic Needle, Low dead-space 29G × 1/2" (0.33 × 13mm) Red
N27150L	Prosum Hypodermic Needle, Low dead-space 27G × 1 1/2" (0.4 × 38mm) Gray
N27034L	Prosum Hypodermic Needle, Low dead-space 27G × 3/4" (0.4 × 19mm) Gray
N27050L	Prosum Hypodermic Needle, Low dead-space 27G × 1/2" (0.4 × 13mm) Gray
N26058L	Prosum Hypodermic Needle, Low dead-space 26G × 5/8" (0.45 × 16mm) Brown
N26050L	Prosum Hypodermic Needle, Low dead-space 26G × 1/2" (0.45 × 13mm) Brown
N26038L	Prosum Hypodermic Needle, Low dead-space 26G × 3/8" (0.45 × 10mm) Brown
N25150L	Prosum Hypodermic Needle, Low dead-space 25G × 1 1/2" (0.5 × 38mm) Orange
N25100L	Prosum Hypodermic Needle, Low dead-space 25G × 1" (0.5 × 25mm) Orange
N25058L	Prosum Hypodermic Needle, Low dead-space 25G × 5/8" (0.5 × 16mm) Orange
N24100L	Prosum Hypodermic Needle, Low dead-space 24G × 1" (0.55 × 25mm) purple
N23150L	Prosum Hypodermic Needle, Low dead-space 23G × 1 1/2" (0.6 × 38mm) Blue
N23125L	Prosum Hypodermic Needle, Low dead-space 23G × 1 1/4" (0.6 × 32mm) Blue
N23100L	Prosum Hypodermic Needle, Low dead-space 23G × 1" (0.6 × 25mm) Blue
N23058L	Prosum Hypodermic Needle, Low dead-space 23G × 5/8" (0.6 × 16mm) Blue
N23034L	Prosum Hypodermic Needle, Low dead-space 23G × 3/4" (0.6 × 19mm) Blue
N34020L	Prosum Hypodermic Needle, Low dead-space 34G × 2mm Orange
N34040L	Prosum Hypodermic Needle, Low dead-space 34G × 4mm Orange
N33020L	Prosum Hypodermic Needle, Low dead-space 33G × 2mm Black
N33040L	Prosum Hypodermic Needle, Low dead-space 33G × 4mm Black
N32020L	Prosum Hypodermic Needle, Low dead-space 32G × 2mm Deep Green
N32040L	Prosum Hypodermic Needle, Low dead-space 32G × 4mm Deep Green
N31020L	Prosum Hypodermic Needle, Low dead-space 31G × 2mm White
N31040L	Prosum Hypodermic Needle, Low dead-space 31G × 4mm White
N30020L	Prosum Hypodermic Needle, Low dead-space 30G × 2mm Yellow
N30040L	Prosum Hypodermic Needle, Low dead-space 30G × 4mm Yellow
100/box, 5000/case	

1.2 Material

Component	Material
Needle tube	Stainless steel
Needle hub	Polypropylene
Adhesive	Epoxy

Protective cap	Polypropylene
Safety protective cap	Polypropylene
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

Reference	Description
ISO 7864:2016	Sterile hypodermic needles for single use
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
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
EN 1041:2008+A1:2013	Information Supplied by the Manufacturer with Medical Devices
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 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
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
ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
ISO 6009:2016	Hypodermic needles for single use - Colour coding for identification
ISO 23908:2011 (for safety hypodermic needle variants)	Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

1.9 Classification

Class IIa Sterile Medical Device under

- Rule 6, Annex IX of Medical Devices Directive 93/42/EEC.
- Rule 6, Annex II of UK MDR2002

2. CAUTION

- Do not reuse.
- Do not use if the package is damaged or open, or it is over expiry date.
- After injection, discard safely in accordance with facility protocol.
- Reuse of these single use devices will lead to safety issues, possible infections, and non-function.
- Keep in a cool, dry place, away from chemical substances.
- This device is intended to be used by trained clinicians.

3. HANDLING OF SHARPS

- Handle with care to avoid needlesticks.
- DO NOT RECAP NEEDLES.
- If recapping or removing the needle from its holder or syringe is unavoidable, one-handed method must be utilised, never use a two-handed method.
- Promptly discard the device in a sharp bin according to the relevant local guidelines.
- The sharp must not be bent, broken or re-sheathed prior to disposal.
- For safety device, do not attempt to deactivate the safety by forcing the needle out of the safety sheath.

4. STORAGE CONDITIONS

Store in a dry environment and keep away from sunlight.

5. Labelling

In accordance with 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



Prosum Medical Limited
Unit 14 Cowley Mill Road, Uxbridge, Greater London, UB8 2DB United Kingdom



Métisce Ltd.
1 Agapinoros, JNT, 1076 Nicosia, Cyprus