PRODUCT DATA SHEET

SINGLE USE ONLY

NIPRO

PRECISION SYRINGE

STERILE, SINGLE-USE PRECISION SYRINGE WITH FIXED NEEDLE FOR INJECTION OF SMALL VOLUMES

NIPRO MEDICAL EUROPE

PRECISION SYRINGE

STERILE, SINGLE-USE PRECISION SYRINGE WITH FIXED NEEDLE FOR INJECTION OF SMALL VOLUMES

- Not made with latex, DEHP, PVC or BPA*
- 31 G ultra sharp three-beveled lancet cut needle to minimize discomfort
- 8 mm exposed needle length
- Smooth plunger movement for accurate injections
- Available in 0,3 ml
- For use by healthcare professionals only

CE 0044

Medical devices
Class IIa
Rule 6

PRODUCT COMPLIANCE

- CE-marked, Medical devices, Class IIa, Rule 6
- Complies with the following norms, directives, and regulations:

  — EN ISO 10993-10:2013
  — EN ISO 9626:2016
  — EN ISO 10993-1:2009/AC2010
  — EN ISO 10993-4:2017
  — EN ISO 10993-5:2009

  — EN ISO 10993-7:2008/AC:2009
  — EN 10993-10:2013
  — EN ISO 10993-11:2018
  — EN ISO 11607-1:2017
  — EN ISO 11135:2014

  — EN ISO 11138-1:2017
  — EN ISO 11138-2:2017
  — EN ISO 15223-1:2016
  — EN 556-1:2001 /AC:2006
  — EN 1041:2008 + A1:2013

- Labels contain 16 languages

MANUFACTURING DETAILS

Legal manufacturer: PT. Nipro Indonesia Jaya

Country of origin: Indonesia

STERILIZATION AND SHELF LIFE

Sterilization

EtO (Ethylene oxide)

STERILE EO

Single-use only

②

Indicator sticker

Each outer box (or shipping carton) contains a chemical indicator that ensures sterility. This indicator comes in the form of a [brown] sticker that turns [green] when sterilized.
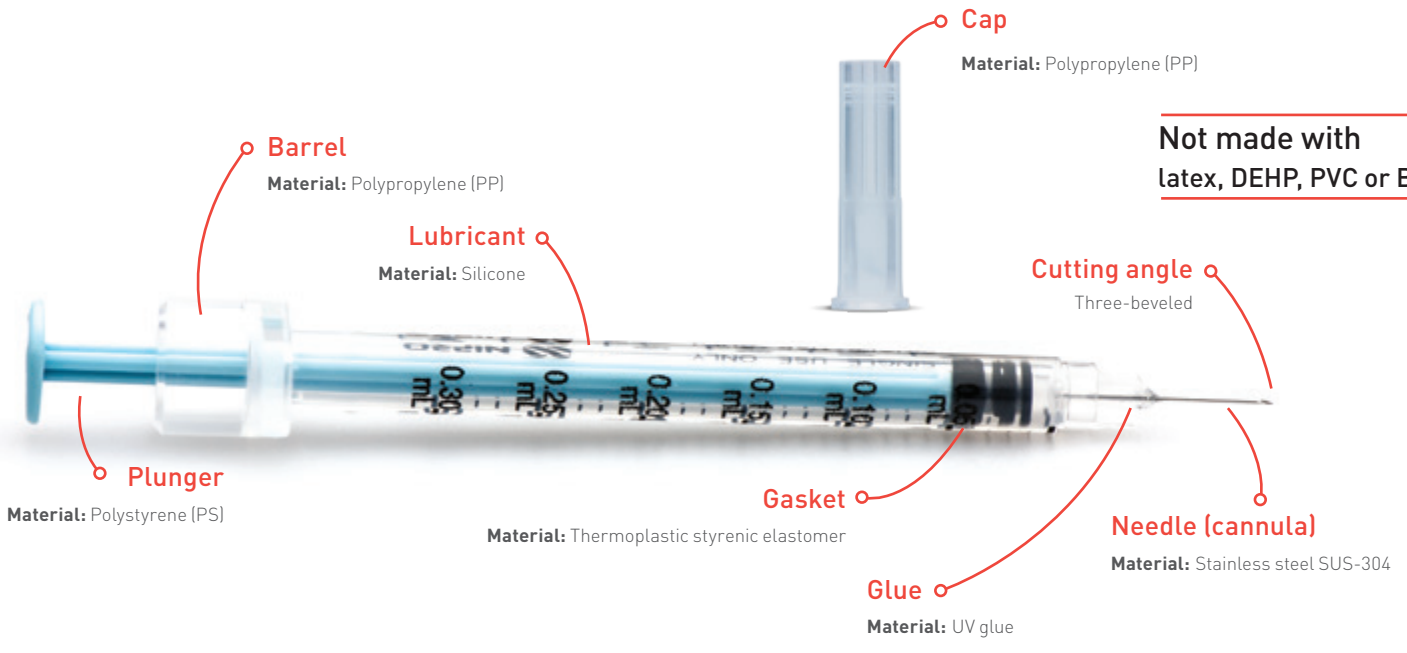
Shelf life

5 years

* below the threshold 0.1 %

MATERIALS USED

Cap
Material: Polypropylene (PP)

Not made with latex, DEHP, PVC or BPA*

Barrel
Material: Polypropylene (PP)

Lubricant
Material: Silicone

Cutting angle
Three-beveled

Plunger
Material: Polystyrene (PS)

Gasket
Material: Thermoplastic styrenic elastomer

Needle (cannula)
Material: Stainless steel SUS-304

Glue
Material: UV glue

PRODUCT RANGE OVERVIEW

Reference code	Description	Dead volume
SYPR-03-3108-EID	Precision syringe 0,3 ml with needle 31 G, 8 mm	0,0011 ml
SYPR-03-ETW-EID	Precision syringe 0,3 ml with ETW needle 31 G, 8 mm	0,0011 ml

PACKAGING DETAILS

Box	Quantity (pcs)	Net weight (kg)	Length (mm)	Width (mm)	Height (mm)	m³
Inner box	100	0,326	—	—	—	—
Outer box	1000	3,27	520	290	185	0,27

Languages

16 languages on all levels of packaging:

Arabic (AR), English (EN), French (FR), Dutch (NL), German (DE), Spanish (ES), Hebrew (HE), Indonesian (ID), Italian (IT), Poland (PL), Portuguese (PT), Greek (EL), Swedish (SV), Danish (DA), Norwegian (NO), and Finnish (FI)

Transport conditions
Closed and dry

Storage conditions
Open packaging only immediately before use to guarantee sterility.

* below the threshold 0.1 %

Label details

	Individual unit	Inner box	Outer box
Product name	✔	✔	✔
Product size	—	✔	✔
Quantity (pieces)	✔	✔	✔
REF	✔	✔	✔
LOT	✔	✔	✔
⧗	✔	✔	✔
STERILE EO	✔	✔	✔
CE	✔	✔	✔
②	✔	✔	✔
⊘	✔	✔	✔
⚕	✔	✔	✔
🏭	✔	✔	✔
EC REP	✔	✔	✔
‖‖‖	—	✔	✔
⚱	—	—	✔
LATEX	✔	✔	✔