PRODUCT DATA SHEET

HOSPITAL PRODUCTS

SAFETOUCH™ WINGED NEEDLE SET

WITH SAFETY DEVICE
INTENDED FOR INFUSION THERAPY

NIPRO MEDICAL EUROPE

SAFETOUCH™ WINGED NEEDLE SET

WITH SAFETY DEVICE INTENDED FOR INFUSION THERAPY

- Irreversible, transparent safety mechanism activated by one hand
- Audible click confirms locking
- Does not require a change in puncture technique
- Ultra sharp three-beveled needle
- Siliconization of needle minimizes penetration and gliding force
- Large soft wings for easy grip
- Color-coded to conform to ISO 6009
- Latex-free, DEHP-free
- For use by healthcare professionals only

CE

Class IIa Medical Devices
Rule 7
MDD 93/42/ECC
UMDNS 12752

PRODUCT COMPLIANCE

- CE-marked, Class IIa Medical Devices, Rule 7, MDD 93/42/ECC, UMDNS 12752
- Complies with the following norms, directives, and regulations:

— ISO 594-1	— ISO 7864	— ISO 10993-7	— ISO 13485
— ISO 594-2	— ISO 8536-4	— ISO 10993-10	— ISO 15223-1
— EN 868-5	— EN ISO 9626 + A1	— ISO 10993-11	
— CSN EN 1707	— ISO 10993-4	— ISO 11607-1	
— ISO 6009	— ISO 10993-5	— ISO 11607-2	

- Labels contain 12 languages

MANUFACTURING DETAILS

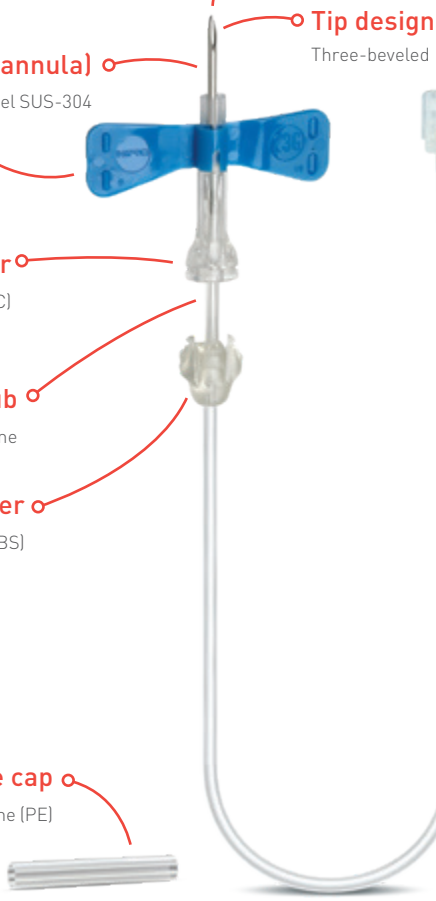
Legal manufacturer: Nipro Corporation

Country of origin: Thailand

STERILIZATION AND SHELF LIFE

Sterilization	Single-use only	Indicator sticker	Shelf life
EtO (Ethylene oxide) STERILE EO		Each outer box (or shipping carton) contains a chemical indicator that ensures sterility. This indicator comes in the form of a blue sticker that turns red when sterilized.	5 years

MATERIALS USED



DEHP-free
Latex-free

PRODUCT RANGE OVERVIEW

Reference code	Description	Tubing length	Purpose	Color	Flow rate not less than	Priming volume
PSV-SF-19-ET	Safety Winged Needle Set 19 Gx19 mm	300 mm	IV/SC		36,5 ml/min	0,56 ml
PSV-SF-21-ET	Safety Winged Needle Set 21 Gx19 mm	300 mm	IV/SC		20 ml/min	0,56 ml
PSV-SF-22-ET	Safety Winged Needle Set 22 Gx19 mm	300 mm	IV/SC		12 ml/min	0,56 ml
PSV-SF-23-ET	Safety Winged Needle Set 23 Gx19 mm	300 mm	IV/SC		7,8 ml/min	0,56 ml
PSV-SF-25-ET	Safety Winged Needle Set 25 Gx19 mm	300 mm	IV/SC		3,7 ml/min	0,56 ml

IV: Intravenous, SC: Subcutaneous, SF: SafeTouch, E: Ethylene Oxide, T: Thailand

PACKAGING DETAILS

Box	Quantity (pcs)	Net weight (kg)	Gross weight (kg)	Length (mm)	Width (mm)	Height (mm)	m^3
Inner box	50	—	—	215	120	102	—
Outer box	500	3,24	3,74	532	256	244	0,033

Languages

12 languages on IFU, and all levels of packaging:

English (EN), French (FR), Dutch (NL), German (DE), Spanish (ES), Italian (IT), Portuguese (PT), Greek (EL), Swedish (SV), Danish (DA), Norwegian (NO), and Finnish (FI)

Transport conditions

Closed and dry

Storage conditions

Open the packaging only immediately before use to guarantee sterility. Store in a dry place away from direct heat and sunlight.

Label details

	Individual unit	Inner box	Outer box
Product name	✓	✓	✓
Product size	✓	✓	✓
Quantity (pieces)	—	✓	✓
REF	—	✓	✓
LOT	✓	✓	✓
	✓	✓	✓
STERILE	✓	✓	✓
CE	✓	✓	✓
	✓	✓	✓
	✓	✓	✓
	✓	✓	✓
	✓	✓	✓
EC REP	✓	✓	✓
	—	✓	✓
	✓	✓	✓
	✓	✓	✓
	✓	✓	✓

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