

## Sterile Single Use Insulin Pen Needle



### 1 USAGE FEATURES\*

Intended Use:

It is intended for injecting insulin with insulin pen for the patients needing insulin.

\*: Product features may vary depending on the intended use and usage of the product.

1.1	Recommended usage period	Transient
1.2	Usage	<input checked="" type="checkbox"/> Invasive <input type="checkbox"/> Non invasive
1.3	Ergonomical features	Atraumatic tip design
1.4	Patient and user safety	The product is a single use product and requird warnings about the reuse of the product is prepared as an insert IFU.

## 2 PRODUCT RANGE

	Gauge	31G	32G
2.1	Length	31 (0,25)x4mm	32 (0,23)x4mm
		31 (0,25)x5mm	
		31 (0,25)x6mm	
		31 (0,25)x8mm	

## 3 PRODUCT COMPONENTS

3.1	Protective Cap Material	PP – Polypropylene
3.2	Adhesive Material	Epoxy
3.3	Needle Hub Material	SS304 Stainless Steel
3.4	Needle Material	PP – Polypropylene
3.5	Needle Shield Material	PE – Polyethylene

## 4 REGULATORY INFORMATION

4.1	Related Directive	93/42/EEC Medical Device Directive
4.2	Risk Class and Rule	Ila, Rule 6
4.3	Product Standard	ISO 7864 ISO 9626 ISO 11608
4.4	GMDN Code	35389 Syringe, hypodermic, insulin

## 5 STERILIZATION AND SHELF LIFE

5.1	Sterilization method	EO sterilized
5.2	Shelf Life	5 years

## 6 STORAGE / TRANSPORTATION CONDITIONS

20-80 %RH, 5-35°C

Protect from direct sunlight.

Should be protected from impacts during transportation.

## 7 HISTORY OF DOCUMENT REVISION

Rev. Date	Rev. No	Revision Reason
03.01.2020	00	First published.