Sterile Hypodermic 1ml Syringe for Single Use

1 USAGE FEATURES*

Intended Use:

The Sterile Hypodermic 1 ml Syringe for Single Use is intended to be used for medical purposes to inject tuberculin drug into the body.

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

1.1	Recommended usage period	Transient
1.2	Usage	☐ Invasive ☒ Non invasive
1.3	Ergonomical features	Perfect sealing. Easy and regular sliding of the plunger. No air leakage through gasket and end piece.
1.4	Patient and user safety	The product is for single use only and required warnings about the reuse of the product is prepared as an insert IFU.

PRODUCT DATA SHEET

2 PRODUCT RANGE

2.1	Volume		**1ml**	
2.2	Barrel Marking Specs		0.01 ml	0.05 ml
2.3	Dead Space Volume	Mean	0.029 ml	
		Std. Deviation	0.002 ml	
2.4	Nozzle/Tip Type and Syringe Configuration		Luer, 6% conical, 1.2mm	
			Barrel, Plunger, Plunger Stopper (Gasket)	
2.5	Barrel Transparency		✓	✓
2.7	Length (mm)		87,1	87,1
2.8	Diameter (mm)		6,85	6,85
2.9	Operation Mode		The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	
2.10	Graduation Legibility		Legible	

3 PRODUCT COMPONENTS

3.1	Barrel Material	PP – Polypropylene
3.2	Plunger Material	PP – Polypropylene
3.3	Plunger Stopper (Gasket) Material	Isoprene rubber, Latex free.
3.4	Lubricant Composition	Silicone oil
3.5	Packing Material	Medical grade paper and transparent film for EO (individually blister packed or pack of 10)

4 REGULATORY INFORMATION

4.1	Related Directive	93/42/EEC Medical Device Directive
4.2	Risk Class and Rule	Is, Rule 2
4.3	Product Standard	ISO 7886-1 ISO 80369-7 ISO 8537
4.4	GMDN Code	35904 Syringe, hypodermic, metered-delivery.

5 STERILIZATION AND SHELF LIFE

5.1	Sterilization method	EO sterilized
5.2	Shelf life	5 years

6 STORAGE / TRANSPORTATION CONDITIONS

20-80 %RH, 0-45°C
Protect from direct sunlight.
Should be protected from impacts during transportation.

7 HISTORY OF DOCUMENT REVISION

Rev. Date	Rev. No	Reason for Revision
04.12.2020	00	First published.
11.01.2021	01	Dead space mean and standard deviation values are added.