

Prodotto: **STERILE HYPODERMIC SYRINGE 5ml Luer Lock S/A - PENTA**

 REF: **002022520F**

 CND: **A020102020102**

Components	Technical specifications (Applied standards)	Materials
Plunger	Distance push-button/finger grips: min 8 mm (ISO 7886-1)	Opaque polypropylene
Barrel	Usable capacity : min 5.5 ml Luer taper 6% (ISO 80369-7) Graduated scale interval: 0,2 ml (ISO 7886-1) Numbered scale: every 1 ml (ISO 7886-1) Tolerance on any graduated capacity greater than 2.5 ml: +/- 5% (ISO 7886-1) Lubrication: maximum quantity 0,25 mg/cm ² of internal surface (ISO 7886-1)	Polipropilene trasparente Black ink Silicone oil (polydimethylsyloxane)
Rubber gasket	Black color; two sealing rings	Synthetic rybber (latex free)
Assembled syringe	Watertight under compression: min 300 kPa (ISO 7886-1) Dead space: max. 0,07 ml (ISO 7886-1) Retaining ring	
Sterile barrier system (primary packaging)	Paper : 60 g/m ² Film : spessore 80 µm Opening type: PEEL Variable data: product description , LOT, REF./code, expiry date	Medical grade paper Plastic film
Inner box	Pieces/box: 100 Ext. dimensions (in mm): 431 x 138 x 87 Variable data: product description , LOT, quantity REF./code, expiry date, Data-matrix	Corrugated cardboard with white outer cover
Outer box	Number of inner boxes /outer box: 16 (1600 total pcs) Ext. dimensions (in mm): 586 x 375 x 447 Labelling: data: product description , LOT, quantity, REF./code, expiry date, Data-matrix, sterilization cycle number	Corrugated cardboard with white outer cover
Sterilizzazione	Mixture: Ethylene Oxide 10 % + CO ₂ 90% Sterilization chambers capacity: 24 m ³ + 40 m ³ Cycle validated according to the standard EN ISO 11135 Shelf life: 5 years, if the sterile barrier system is undamaged and correctly stored	

DEHP FREE – PVC FREE- LATEX FREE device

Keep the product away from direct exposure to sunlight, in dry and clean environments and away from extreme temperatures and excessive humidity

 Issue :
 Quality & Regulatory Manager
 ROSA DI GIOIA



Last review: 1/02/2019

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 Rev.01