

TECHNICAL DATA SHEET

Codice: **LPE05**
 Prodotto: **Enteral syringe ENFit 5 ml**
 Volume: **5 ml**
 Classe CE: **Ila**

DEHP FREE



COMPONENTS	SPECIFICS (APPLICABLE STANDARDS)	RAW MATERIALS
Plunger	Distance finger grip - barrel /finger grip (ISO 7886-1): 14 mm ca.	Polypropylene + Colorant Purple Master Batch
Barrel	Female connector ENFit , designed in compliance with ISO 80369-3 standard in order to avoid any possible <i>misconnection risk with parenteral devices</i> (wrong connection with different administration ways than the enteral ones) Scale increment (ISO 7886-1): 1 ml Tolerance on the nominal delivered capacity (ISO 7886-1): +/- 4% Lubrication (ISO 7886-1): max. quantity 0.25 mg/cm ² of internal surface	Transparent polypropylene Black ink Silicone oil
Piston	Colour: black; two retaining rings	Latex free synthetic rubber
Packaging	The packaging will consist of Blister pack-paper and with transparent plastic film which will have a peel opening. Labeling: Product description , Batch number, Expiry date, Item code	Medical grade paper Plastic Film
Box	Number of pieces per box: 100 Labeling: Product description , Q.ty, Batch number, Expiry date, Barcode, Item code	Corrugated cardboard
Carton	Numero di scatole per cartone: 16 Dati riportati sull'etichetta: Disegno prodotto, Descrizione prodotto, Quantità, Numero lotto, Data scadenza, codice a barre, Codice prodotto, Numero ciclo di sterilizzazione	White Corrugated cardboard
Palletization	Total cartons on pallet: 15	Pallet dimensions: 80 x 120 cm
Sterilization	ETO Sterilised Cycle validated according to Standard EN ISO 11135-1 "Medical devices sterilization - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices". Shelf-life of the product: 5 years if the packaging is undamaged.	
Storage	Store the product away from direct sunlight, in a clean and low humidity environment.	

Registration to Italian Medical Devices Repertoire

CND: **A020299**
 RDM: **1540936**
 GMDN: **59040**

GTIN – UDI

PACKAGING: **05060278507422**
 BOX: **25060278507426**
 CARTON: **45060278507420**

EU Rep



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