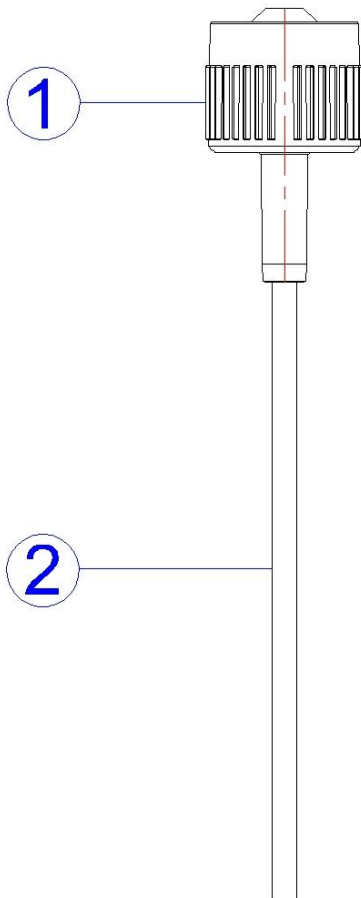


TECHINICAL DATA SHEET

ENFit MEDICINE STRAW



● PRODUCT COMPOSITION:

1. **ENFit** Small Bore male connector in purple **ABS**, produced in compliance with ISO 80369-3 norm.
2. Tube in **PVC DEHP FREE**, Ø 1x 2 mm and length cm. 5.

● INTENDED USE:

Safe drawing and delivery of small medicine volumes, both orally or through an enteral feeding set.

● PACKAGING:

Single packaging in Paper/PP-PE film Blister. Multiple package 50 Pcs.

● PRODUCTION PROCESS:

The device is manufactured in accordance with the Quality System of HMC Premedical SpA in compliance with the requirements of the standard EN ISO 13485.

● CONTROL ON THE PRODUCT:

In all stages of processing, such as internal procedures and according to ISO 2859-1 sampling plans.

● CLASSIFICATION:

Class IIa sterile.

● STERILIZATION:

Product sterilized by ethylene oxide according to a validated course of treatment in accordance with current regulations.

Shelf life 5 years from the date of sterilization.

For single-use only and Non re-sterilizable.

● STORAGE:

Standard storage procedures and conditions.

● DISPOSAL:

The user must follow the legal regulations regarding disposal of hospital waste.

● WARNINGS:

The device must be used exclusively by healthcare professionals.

● REGISTRATION TO ITALIAN M.D. REPERTOIRE:

no. CND: **A030403** – no. RDM: **1573688**

DEHP FREE



CODE	BOX Pcs.
C005L	50

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – English language	08/04/2016	E. Benassi	D. Bosetti
01	Product Composition updated	27/07/2016	E. Benassi	D. Bosetti
02	Sheet updated as HMC; Classification, CND and RDM updated	12/10/2017	E. Benassi	D. Bosetti