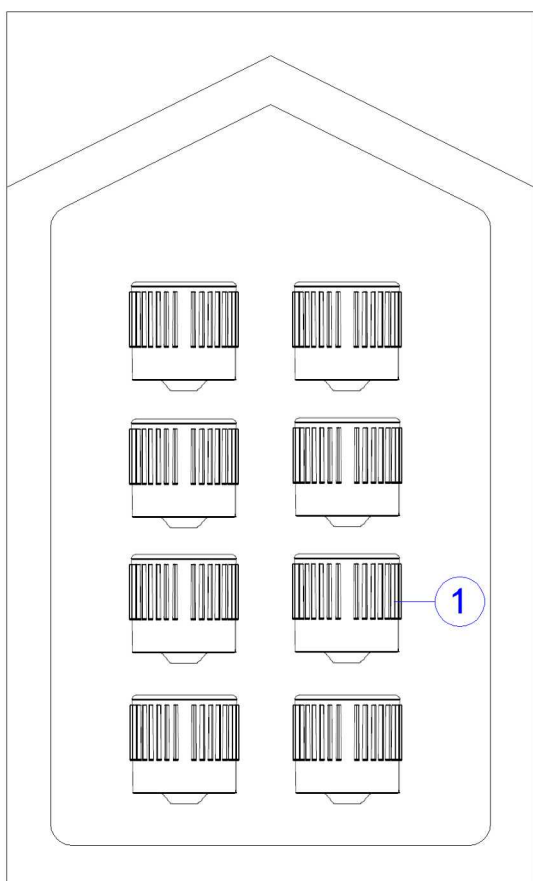


TECHNICAL DATA SHEET

PURPLE MALE ENFit LOW DOSE CAP (pack of 8)



● PRODUCT COMPOSITION:

1. Closed male **ENFit Low Dose** cap in purple **PP** (pack of 8), produced in compliance with ISO 80369-3 norm.

● INTENDED USE:

ENFit Low Dose male cap is used mainly to close-off ENFit Low Dose Tip syringes; it is also compatible with all female ENFit connectors.

● PACKAGING:

Single packaging: 8 pcs. in Paper/PP-PE film Blister.
Multiple package of 50 blisters.

● PRODUCTION PROCESS:

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

● CONTROL ON THE PRODUCT:

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

● CLASSIFICATION:

Class IIa sterile.

● STERILIZATION:

Product sterilized by Ethylene Oxide (EO) 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.
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: **A0880** – no. RDM: **1572532**

DEHP FREE



CODE	PACKAGE pcs.	BOX pcs.
M158/8LD	8	50

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – english language	10/10/2016	E. Benassi	D. Bosetti
01	Sheet updated as HMC; Classification and RDM updated	13/10/2017	E. Benassi	D. Bosetti