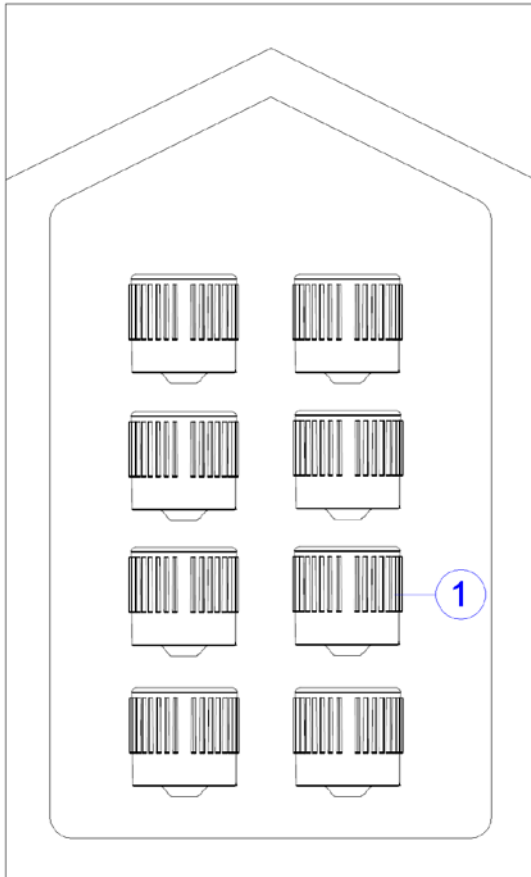


# PRODUCT TECHNICAL DATA SHEET

## DESCRIPTION PURPLE MALE ENFit LOW DOSE CAP



**DEHP FREE**

CODE	BOX pcs.	CARTON pcs.
M158/8LD	50 blisters (400 caps)	400 blisters (3200 caps)

# PRODUCT TECHNICAL DATA SHEET

## ● PRODUCT COMPOSITION:

1. Closed male **ENFit Low Dose** cap in purple **Polypropylene**, 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:

Primary package: single product in medical grade paper/Film **PP-PE** Blister.

Each blister contains **8 caps**.

Secondary package: box with 50 blisters; carton with 400 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 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 MEDICAL DEVICES REPERTOIRE:

CND: **A0880**

RDM: **1572532**

GMDN: **65012**

## ● UNIT OF SALE:

Carton with **3200 pieces**.

## ● UDI:

Single product: **05060278509327**

Box: **25060278509321**

Carton: **45060278509325**

REV.	CHANGES	ISSUED	VERIFIED AND APPROVED	DATE
00	First issue – english language	E. Benassi	D. Bosetti	10/10/2016
01	Sheet updated as HMC; Classification and RDM updated	E. Benassi	D. Bosetti	13/10/2017
02	Packaging updated	E. Benassi	S. Tralli	15/04/2020
03	Manufacturer's legal address update	E. Benassi	S. Tralli	18/05/2021
04	Data sheet update	E. Benassi	S. Tralli	05/01/2022