

TECHNICAL DATA SHEET

WHITE FEMALE ENFit CAP

● PRODUCT COMPOSITION:

1. Closed female **ENFit** cap in white **DEHP FREE PVC**, produced in compliance with ISO 80369-3 norm.

● INTENDED USE:

The cap is used to close-off lines on enteral nutrition systems which are equipped with ENFit male connectors.

● PACKAGING:

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

● 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 Is 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:

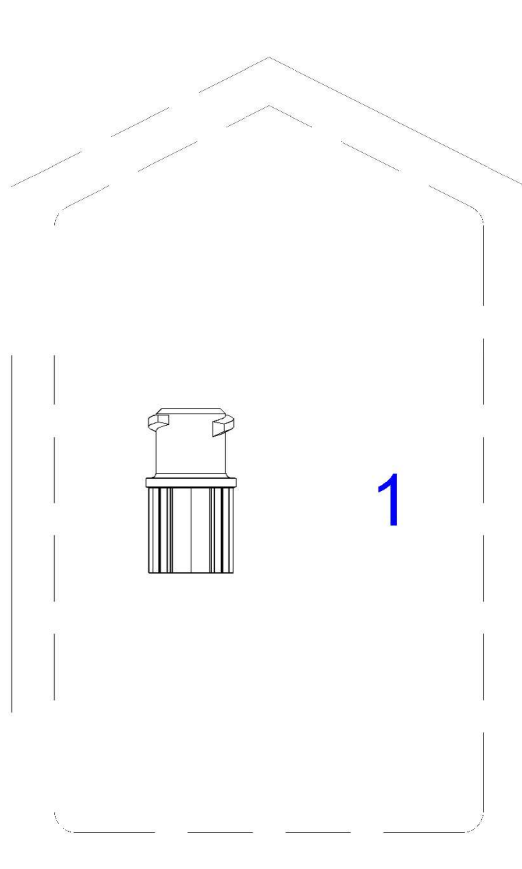
The user must follow the legal regulations regarding disposal of hospital waste.

● 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	BOX pcs.
ML02L	50

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – English language	07/05/2018	E. Benassi	D. Bosetti