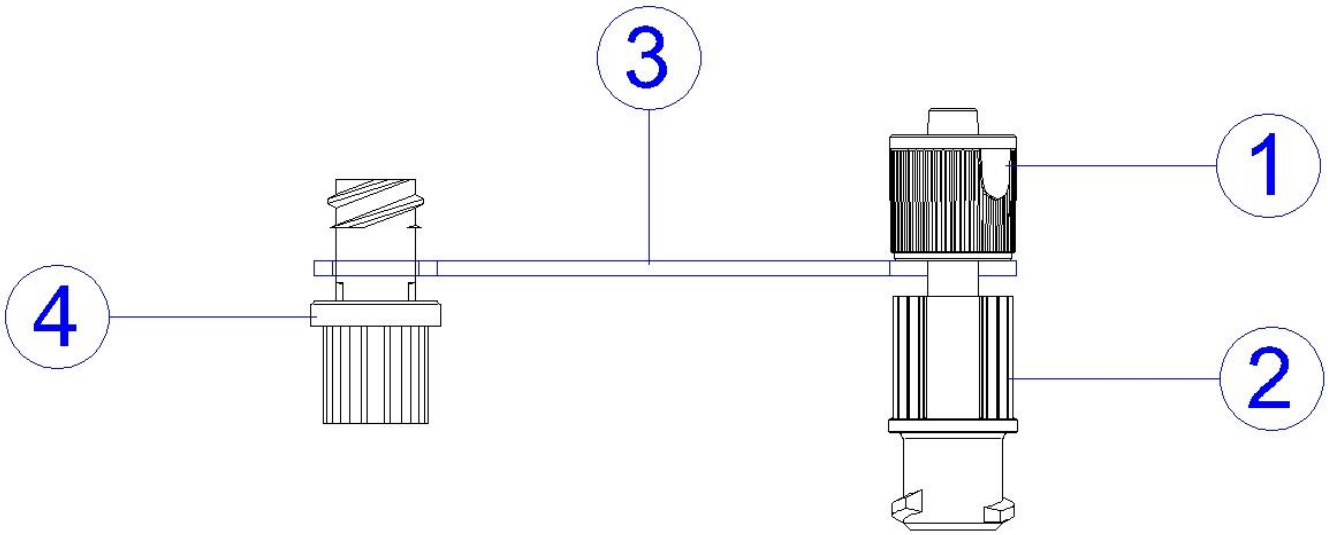
HMC Premedical SpA
Via Tonino Morandi, 16 - 41037 MIRANDOLA (MO) ITALY Tel. 0535 22704 - Fax. 0535 609546 info@hmcgroup.it

CE 0051

TECHNICAL DATASHEET

ENFit tube to reverse luer syringe adapter - ISO 80369-3



DEHP FREE

LATEX

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PRODUCT COMPOSITION:

1. M.L.L. connector in purple **ABS**.
2. Female ENFit small bore connector in purple **PVC DEHP FREE**, produced in compliance with ISO 80369-3 norm.
3. Strap in purple **PVC DEHP FREE**.
4. F.L.L. closed cap in white **PP**.

INTENDED USE:

Drawing and transfer of enteral feeding solutions.

PACKAGING:

Single package in paper/ Film PP-PE Blister.
Multiple package: 50 pcs.

PRODUCTION PROCESS:

The device is manufactured in accordance with HMC Premedical S.p.A. Quality System and in comply with the requirements of the standard EN ISO 13485.

CONTROL ON THE PRODUCT:

In all stages of processing, according to internal procedures and to sampling plans defined by norm ISO 2859-1.

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.
Non re-sterilizable.

STORAGE:

Standard storage procedures and conditions.

DISPOSAL:

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

WARNING:

The device must be used exclusively by healthcare professionals.

REGISTRATION TO ITALIAN M.D. REPERTOIRE:

NR. CND: **A0880** – NR. RDM: **1572532**

CODE	BOX Pcs.
TA02	50

REV. *Rev.*	***MODIFICHE*** *Changes*	**DATA** *Date*	**EMESSO** *Issued*	***VERIFICATO e APPROVATO*** *Verified and Approved*
00	English Languade - First Issue	06/12/2016	E. Benassi	D. Bosetti
01	Data sheet updated to HMC, RDM number update	13/10/2017	E. Benassi	D. Bosetti