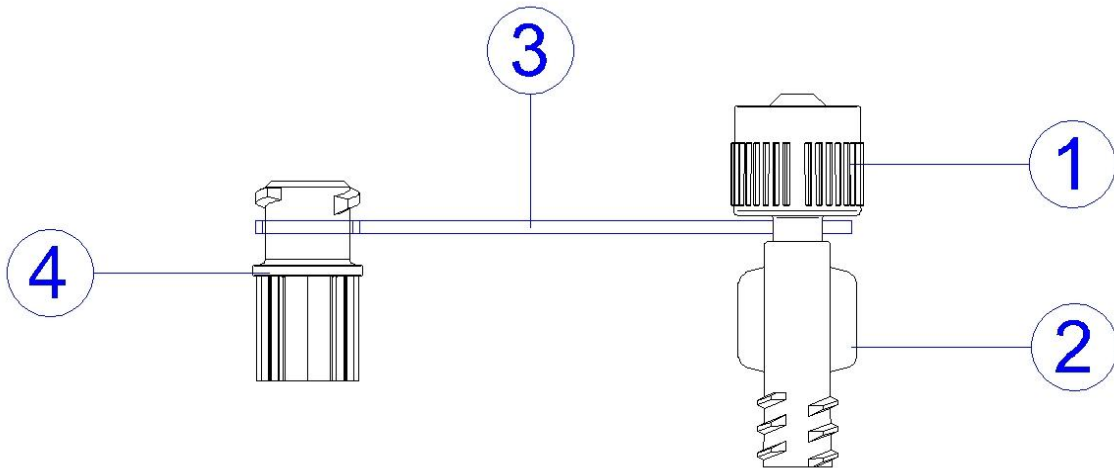


TECHNICAL DATA SHEET

Reverse luer to ENFit syringe transition adapter - ISO 80369-3



DEHP FREE



HMC Premedical SpA

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● PRODUCT COMPOSITION:

1. **ENFit** small bore male connector in purple **ABS**, produced in compliance with ISO 80369-3 norm.
2. Female luer lock connector in purple **DEHP FREE PVC**.
3. Strap in white **DEHP FREE PVC**.
4. Closed **ENFit** female cap in white **DEHP FREE PVC**, produced in compliance with ISO 80369-3 norm.

● 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 Q.TY pcs.
TA01	50

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – english language	13/01/2016	E. Benassi	D. Bosetti
01	Data sheet updated to HMC, RDM number update	13/10/2017	E. Benassi	D. Bosetti