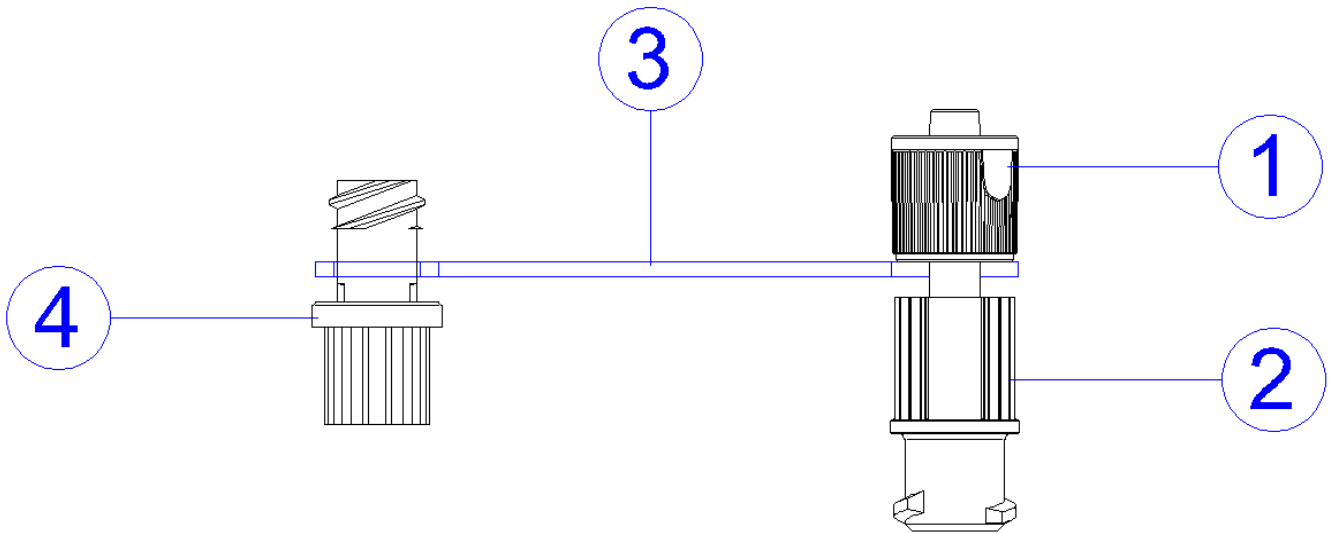


# PRODUCT TECHNICAL DATA SHEET

## DESCRIPTION

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



**DEHP FREE**

CODE	BOX Pcs.	CARTON pcs.
TA02	50	400

# PRODUCT TECHNICAL DATA SHEET

## ● 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 **Polypropylene**.

## ● INTENDED USE:

Drawing and transfer of enteral feeding solutions.

## ● PACKAGING:

Primary packaging: single product in medical paper/PP-PE film Blister.  
Secondary packaging: box with 50 pcs; carton with 400 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 and 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 MEDICAL DEVICES REPERTOIRE:

CND: **A0880**

RDM: **1572532**

GMDN: **n/a**

## ● UNIT OF SALE:

Carton with **400 pieces**.

## ● UDI:

Single product: **05060278508856**

Box: **25060278508850**

Carton: **45060278508854**

REV.	CHANGES	ISSUED	VERIFIED AND APPROVED	DATE
00	English Language - First Issue	E. Benassi	D. Bosetti	06/12/2016
01	Data sheet updated to HMC, RDM number update	E. Benassi	D. Bosetti	13/10/2017
02	Packaging updated	E. Benassi	S. Tralli	15/04/2020
03	Data sheet update	E. Benassi	S. Tralli	10/01/2022