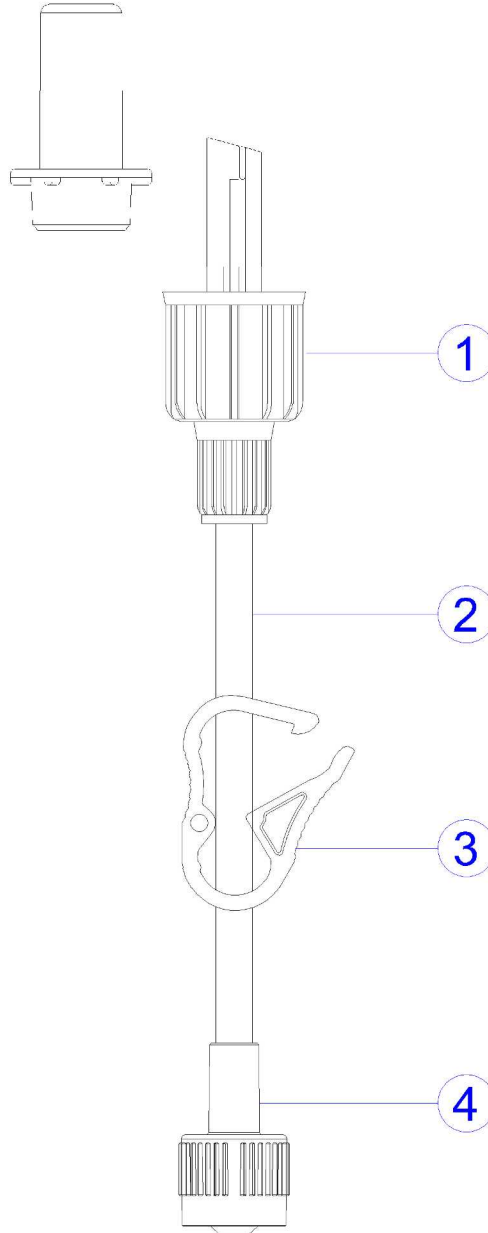


## TECHNICAL DATASHEET

### Pre-filled bag adapter - ENFit syringe to ENPlus cross spike



DEHP FREE



### ● PRODUCT COMPOSITION:

1. ENPlus cross spike connector in purple **ABS** with protective cap in **PE**.
2. Tube in clear **DEHP FREE PVC**, Ø 2,7x4,15 mm and length 6 cm.
3. Small pinch clamp in white **PP**.
4. **ENFit** male connector in purple **ABS**, produced in compliance with ISO 80369-3 norm.

### ● INTENDED USE:

The device can be used to transfer feeding solutions from enteral feed bags to ENFit syringes.

### ● PACKAGING:

Single package in paper/ Film PP-PE Blister.  
Multiple package of 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.
SA01L	50

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – English language	09/11/2017	E. Benassi	D. Bosetti