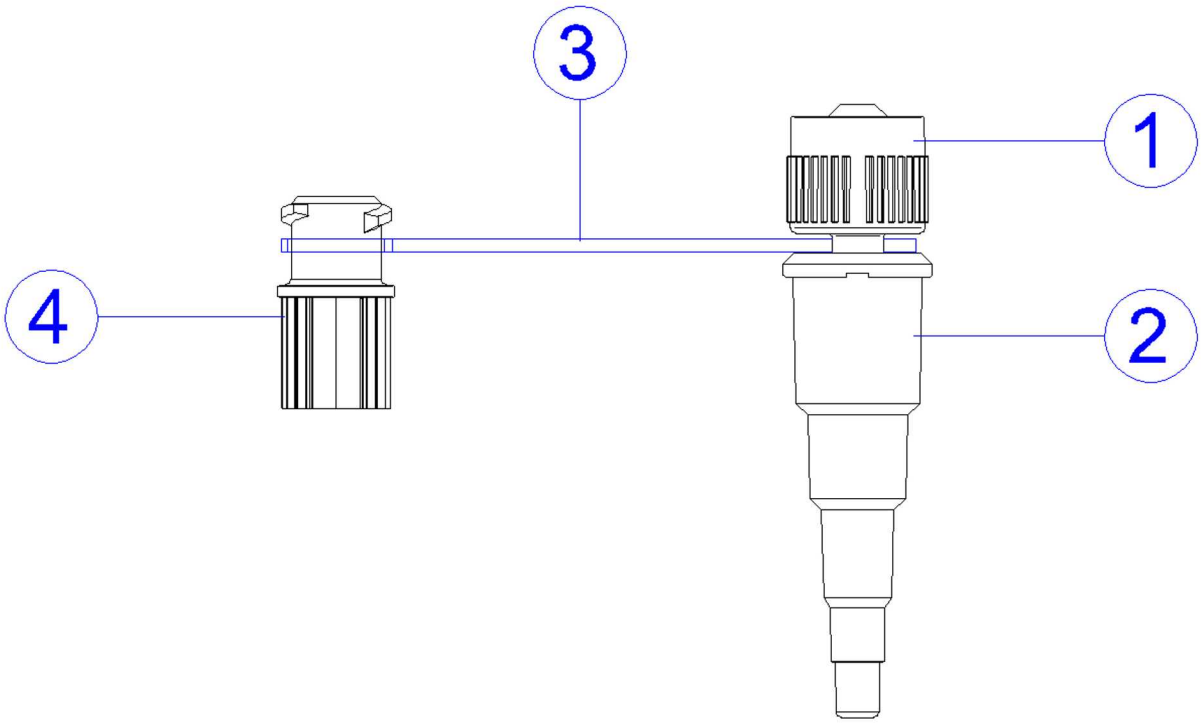
HMC Premedical SpA
Via Tonino Morandi 16, - 41037 MIRANDOLA (MO) ITALY Tel. 0535 22704 - Fax. 0535 609546 info@hmcgroup.it

CE 0051

TECHNICAL DATASHEET

ENFit ISO 80369-3 Transition adapter - Funnel tube to ENFit syringe/set



DEHP FREE

LATEX

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PRODUCT COMPOSITION:

1. **ENFit** small bore male connector in purple **ABS,** produced in compliance with ISO 80369-3 norm.
2. IVI connector for fixed male luer, 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:
Normal 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 REPERTOIRE:
NR. CND: **A0880** – NR. REPERTORIO: **1572532**

CODE	BOX Pcs.
LK01	50

REV. *Rev.*	*MODIFICHE* *Changes*	DATA *Date*	EMESSO *Issued*	*VERIFICATO e APPROVATO* *Verified and Approved*
00	First issue – English language	14/06/2016	E. Benassi	D. Bosetti
01	Medical device registration updated	23/06/2017	C. Ferrari	D. Bosetti