

TECHNICAL DATASHEET

ENFit tube to Oral Tip syringe/set transition adapter - ISO 80369-3

● PRODUCT COMPOSITION:

1. Oral tip connector in orange **DEHP FREE PVC**.
2. **ENFit** female connector in purple **DEHP FREE PVC**, manufactured 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:

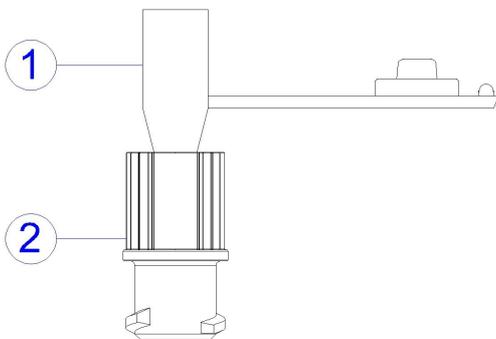
The user must follow the legal regulations regarding disposal of hospital waste.

● WARNING:

The device must be used exclusively by healthcare professionals.

● REGISTRATION TO ITALIAN M.D. REPERTOIRE:

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



DEHP FREE



CODE	BOX Pcs.
TA06	50

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First Issue – English Language	13/10/2017	E. Benassi	D. Boseffi