**HMC Premedical S.p.A.**
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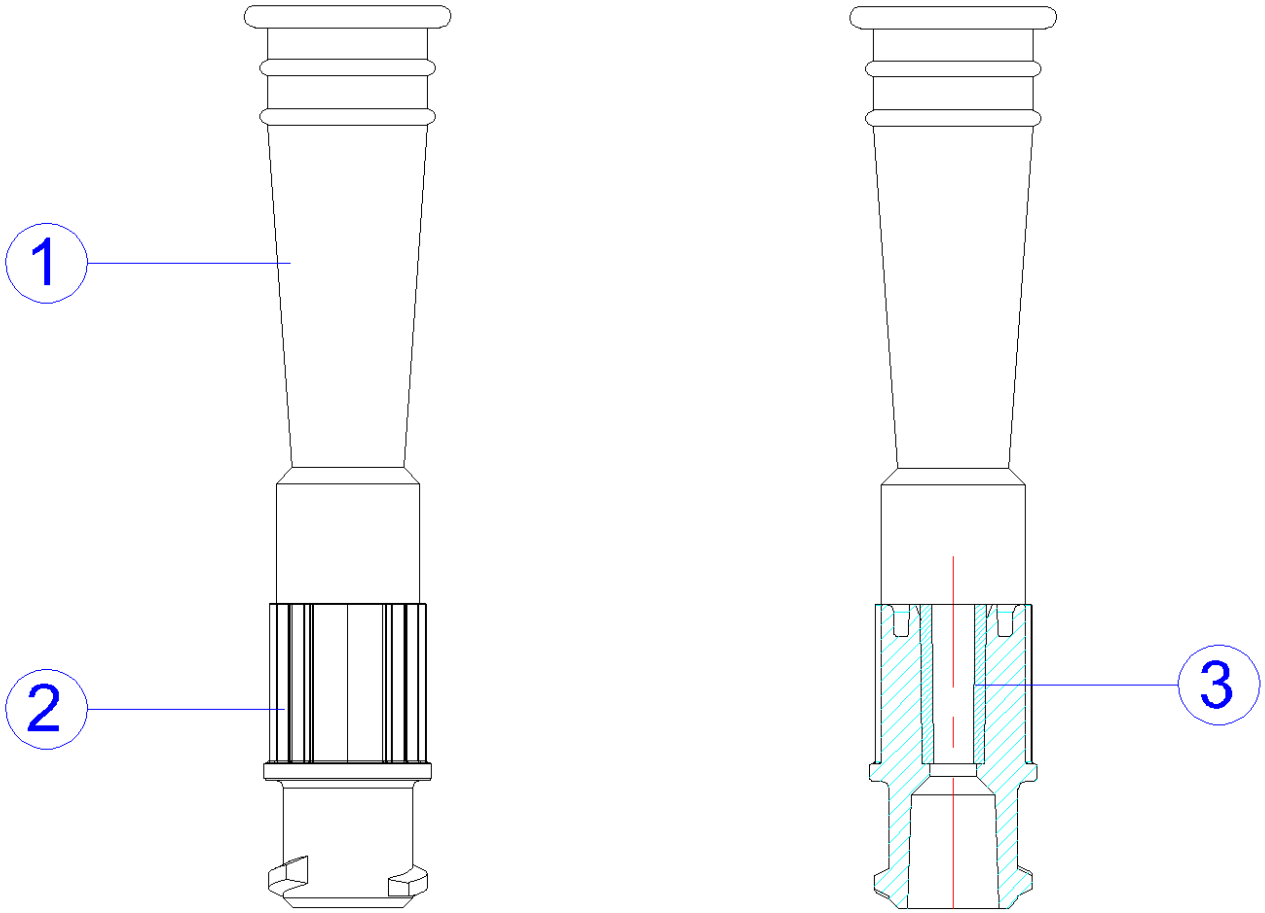
REV. 02 DEL 15/04/2020

CE 0051

# TECHNICAL DATASHEET

## ENFit tube – ENlock Syringe/Set transition adapter - ISO 80369-3




**DEHP FREE**

LATEX

| CODE | BOX pcs. | CARTON pcs. |
|---|---|---|
| TA05 | 50 | 400 |

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## PRODUCT COMPOSITION:

1. "Funnel" connector CH12, in purple **PU**.
2. Female ENFit connector in purple **DEHP FREE PVC**, manufactured in compliance with ISO 80369-3 norm.
3. Tube in **DEHP FREE PVC,** Ø 2,7x4,15 mm and length 1,9 cm.

## 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.
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:

CND: **A0880**
RDM: **1572532**

| **REV.** *Rev.* | ***MODIFICHE*** *Changes* | **DATA** *Date* | **EMESSO** *Issued* | ***VERIFICATO e APPROVATO*** *Verified and Approved* |
|---|---|---|---|---|
| 00 | First issue -. English language | 07/03/2017 | E. Benassi | D. Bosetti |
| 01 | Data sheet updated to HMC, RDM number update | 13/10/2017 | E. Benassi | D. Bosetti |
| 02 | Packaging updated | 15/04/2020 | E. Benassi | S. Tralli |
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