HMC Premedical S.p.A.
Via Tonino Morandi, 16
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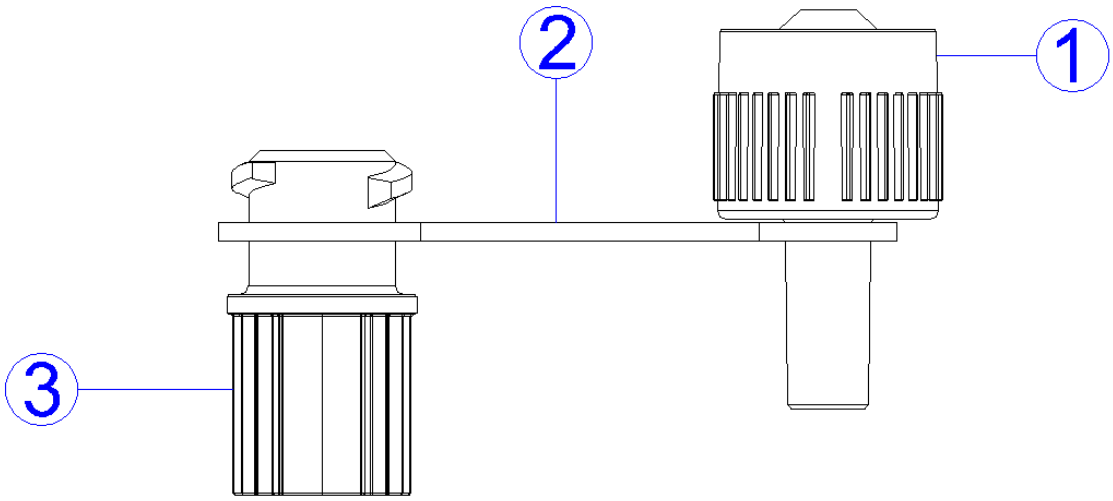
Tel. 0535 22704 - Fax. 0535 609546
info@hmcgroup.it

REV. 01 DEL 15/04/2020

CE 0051

TECHNICAL DATA SHEET

Liquid transfer adapter: Oral tip tube – ENFit Syringe



LATEX

DEHP FREE

CODE	BOX Q.TY pcs.	CARTON pcs.
ML01L	50	400

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PRODUCT COMPOSITION:

1. Small-bore ENFit male connector in purple **ABS**, produced in compliance with ISO 80369-3 norm.
2. Strap in white **DEHP FREE PVC**.
3. ENFit closed female cap in purple **DEHP FREE PVC**, produced in compliance with ISO 80369-3 norm.

INTENDED USE:

Drawing and transfer of 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 the Quality System of HMC Premedical SpA in compliance with the requirements of the standard EN ISO 13485.

CONTROL ON THE PRODUCT:

In all stages of processing, such as internal procedures and according to sampling plans according to 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.

WARNINGS:

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	13/10/2017	E. Benassi	D. Bosetti
01	Packaging updated	15/04/2020	E. Benassi	S. Tralli