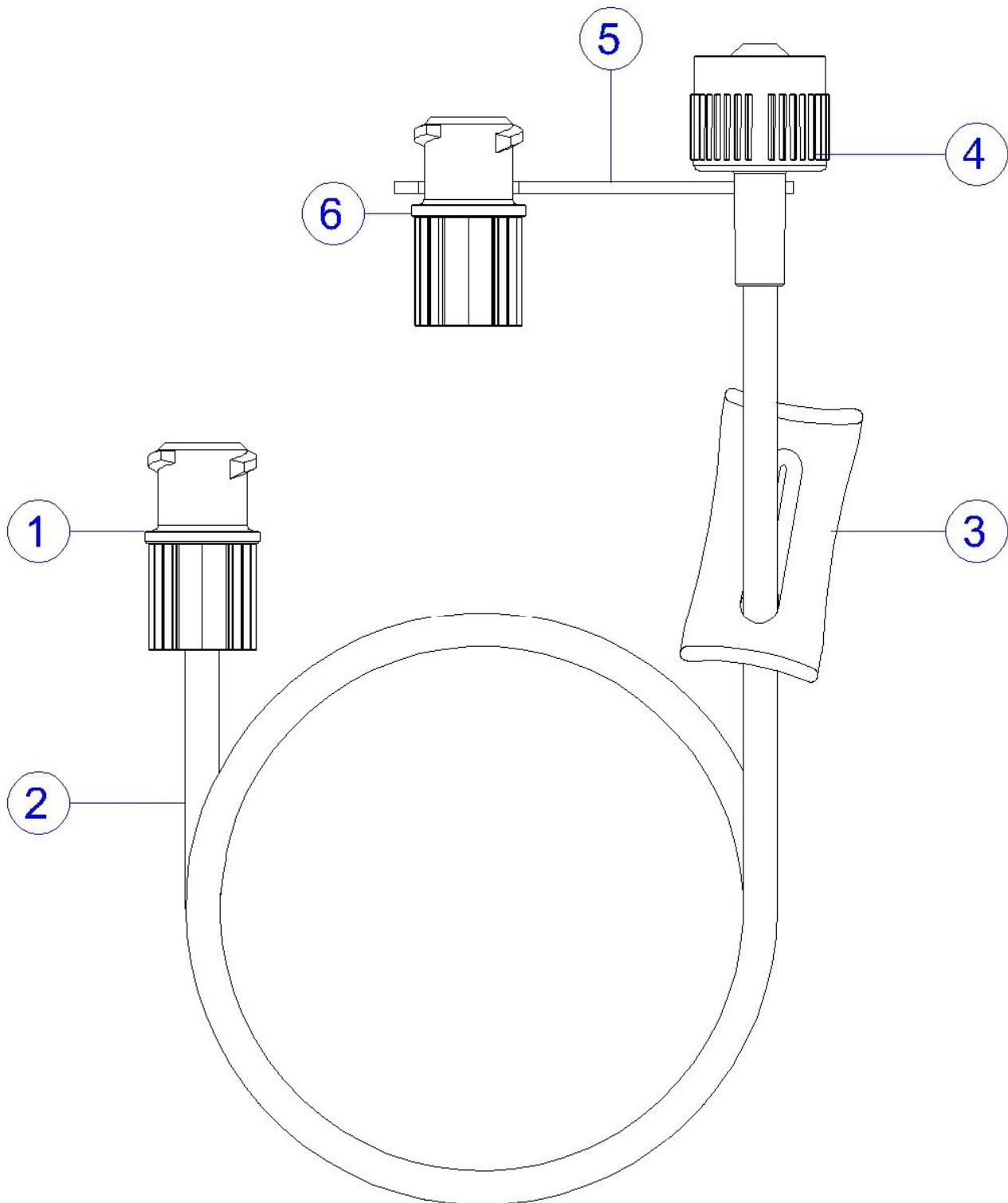


TECHNICAL DATA SHEET

ENFit WIDE BORE EXTENSION LINE - 75 cm



DEHP FREE



HMC PREMEDICAL SPA

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

PRODUCT COMPOSITION:

1. **ENFit** female connector in purple **DEHP FREE PVC**, produced in compliance with ISO 80369-3 norm.
2. Tube in clear **DEHP FREE PVC** with purple stripe, \varnothing 2,7x4,1 mm, length 75 cm.
3. Slide clamp in purple **Polyethylene**.
4. **ENFit** male connector in purple **ABS**, produced in compliance with ISO 80369-3 norm.
5. Strap in white **soft PVC**.
6. Closed **ENFit** female cap in white **DEHP FREE PVC**, produced in compliance with ISO 80369-3 norm.

INTENDED USE:

Extension line for enteral nutrition systems.

PACKAGING:

 Single packaging in Paper/PP-PE film Blister.
 Multiple package 50 pcs.

PRODUCTION PROCESS:

The device is manufactured in accordance with the Quality System 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 and 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 REPERTOIRE:

 NO. CND: **A030403** – NO. RDM: **1573688**

CODE	VOLUME ml	BOX pcs.
EP075LW	4,40	50

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – English Language	13/06/2016	E. Benassi	D. Bosetti
01	Table, Class and RDM number update	03/10/2017	E. Benassi	D. Bosetti