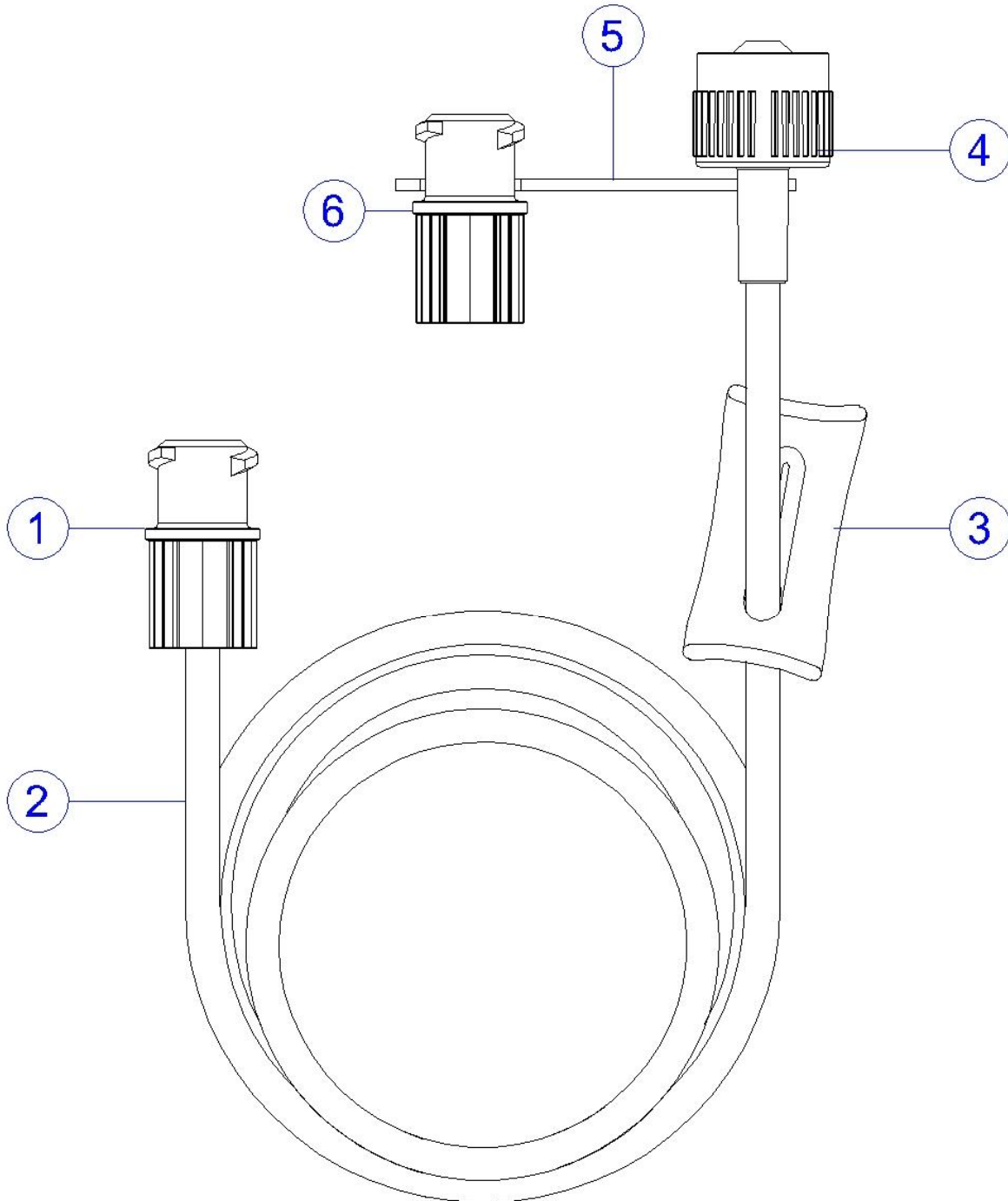


## TECHNICAL DATA SHEET

### ENFit ENTERAL NUTRITION EXTENSION LINE



DEHP FREE



### **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, Ø 1,3x3 mm and variable length (see table below).
3. Slide clamp in purple **Polyethylene**.
4. **ENFit** male connector in purple **ABS**, produced in compliance with ISO 80369-3 norm.
5. White strap in **soft DEHP FREE 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 (See table below).

### **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	LENGTH cm	VOLUME ml	BOX pcs.
EP015L	15	0,30	50
EP075L	75	1,10	50
EP150L	150	2,10	50

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – English language	14/04/2016	E. Benassi	D. Bosetti
01	Product composition update	03/04/2017	E. Benassi	D. Bosetti
02	Table, Class and RDM number update	02/10/2017	E. Benassi	D. Bosetti