

HMC Premedical S.p.A.

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



# TECHNICAL DATA SHEET

# **ENFit MILK STRAW**

### PRODUCT COMPOSITION:

- ENFit L.L.M. connector in purple ABS, produced in compliance with ISO 80369-3 norm.
- 2. Tube in **PVC DEHP FREE**,  $\varnothing$  2,7x4,15 mm, variable length (see table below).

#### **INTENDED USE:**

Safe drawing and delivery of small volumes of medicines, milk or nutritive solutions, both orally or through an enteral feeding set.

### **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 of HMC Premedical SpA in compliance with requirements of standard EN ISO 13485.

#### CONTROL ON THE PRODUCT:

In all stages of processing, such as internal procedures and according to ISO 2859-1 sampling plans.

### CLASSIFICATION:

Class IIa sterile.

## • STERILIZZATION:

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.

## O 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:

no. CND: A030403 - no. RDM: 1573688





CODE	LENGTH cm	BOX Pcs.
C010L	10	50
C014L	14	50
C020L	20	50

REV. Rev.	<b>MODIFICHE</b> Changes	<b>DATA</b> Date	EMESSO Issued	VERIFICATO e APPROVATO  Verified and Approved
00	First issue – English Language	08/04/2016	E. Benassi	D. Bosetti
01	Sheet updated as HMC; Classificatiom, CND and RDM updated	12/10/2017	E. Benassi	D. Bosetti