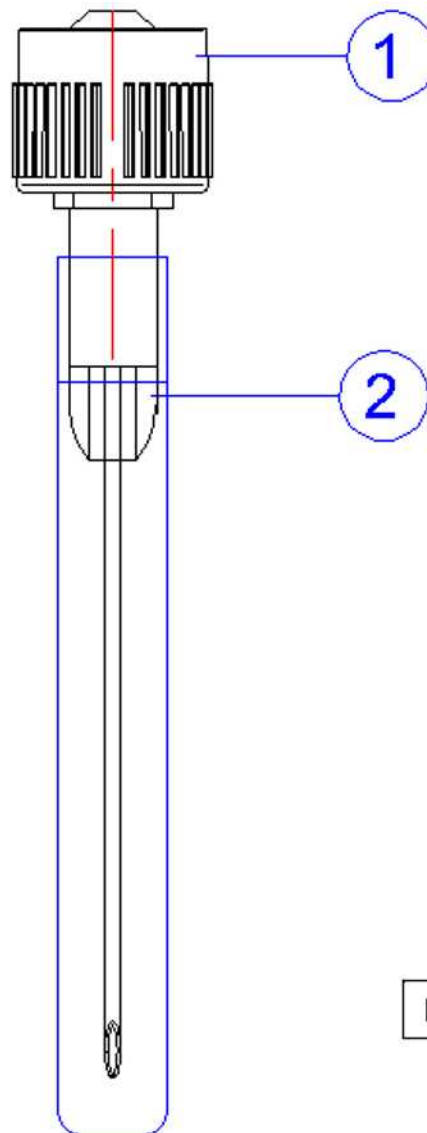


## TECHNICAL DATASHEET

### ENFit Enteral blunt fill needle with filter



DEHP FREE

CODE	BOX pcs.	CARTON pcs.
MN02L	50	200

● **PRODUCT COMPOSITION:**

1. ENFit small bore male connector in purple **ABS**, produced in compliance with UNI CEI EN ISO 80369-3 norm.
2. Blunt needle 18G x 38 mm in **Stainless Steel and Polypropylene**, endowed with a 5 µm fluid filter (not shown).

The device has a needle with **blunt tip at 45 degrees**; compared to a common hypodermic needle, it requires a force only 2.5 times higher to perforate a rubber membrane, and 10 times higher to pierce the human skin. The needle is also endowed with a **5 µm fluid filter**, which enhances patient safety by reducing glass particles contamination of fluids drawn from glass ampoules.

● **INTENDED USE:**

Aspiration of fluids from glass ampoules.

● **PACKAGING:**

Single package in medical grade paper/ Film PP-PE Blister.  
 Multiple package: boxes of 50 pcs; cartons of 200 pcs.

● **PRODUCTION PROCESS:**

The device is manufactured in accordance with HMC Premedical S.p.A. Quality System and in compliance 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 REPERTOIRE:**

CND: **A0880**

RDM: **1572532**

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – English language	01/08/2017	E. Benassi	D. Bosetti
01	Data sheet update	13/10/2017	E. Benassi	D. Bosetti
02	Product composition update	25/08/2018	E. Benassi	D. Bosetti
03	Packaging update; layout revision	20/01/2020	E. Benassi	S. Tralli