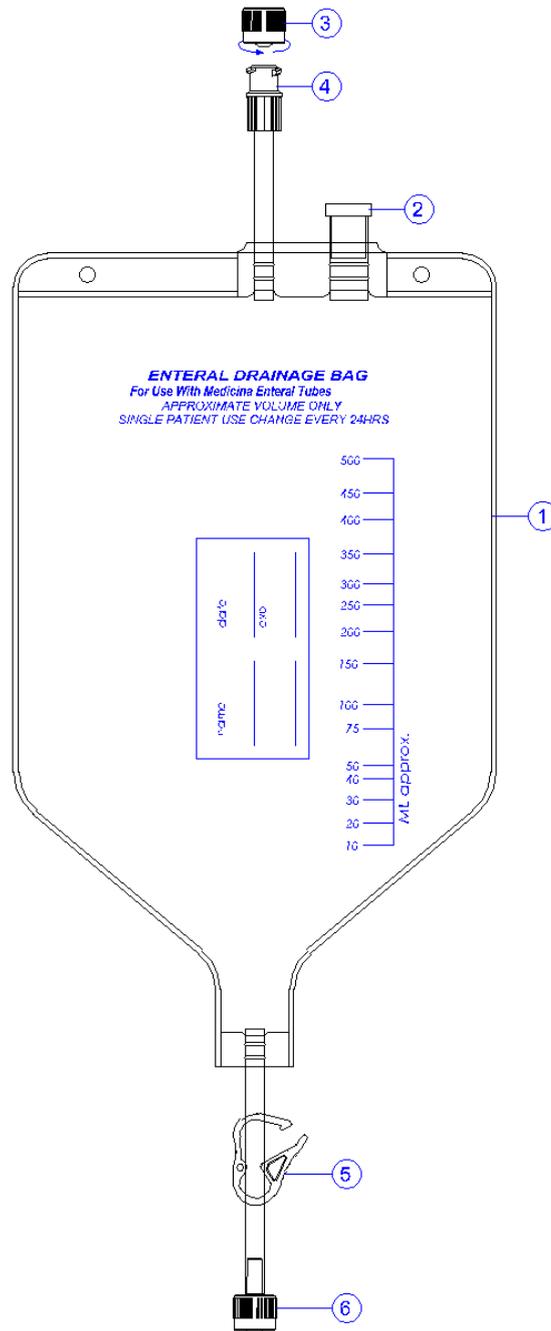


TECHNICAL DATA SHEET

DESCRIPTION ENFit ENTERAL DRAINAGE BAG



CODE	BAG VOLUME ml	BOX pcs.	CARTON pcs.
MED50L	50	25	100
MED100L	100	25	100
MED250L	250	25	100
MED500L	500	25	100
MED1000L	1000	25	100

● PRODUCT COMPOSITION:

1. Enteral drainage bag in **DEHP FREE PVC**, available in various capacities (see table);
2. Bushing in white **ABS** with 3 µm hydrophobic filter;
3. Male ENFit cap in white **ABS**, produced in compliance with ISO 80369-3 norm;
4. Female ENFit connector in purple **DEHP FREE PVC**, produced in compliance with ISO 80369-3 norm;
5. Small pinch clamp in white **Polypropylene**;
6. Male ENFit connector in purple **ABS**, produced in compliance with ISO 80369-3 norm.

● INTENDED USE:

The device is used for stomach decompression and drainage of stomach fluids for testing purpose. An air vent allows any gas to escape should this be required.

● PACKAGING:

Primary packaging: single product in medical Paper/**PP-PE** blister.
Secondary package: box with 25 pcs; carton with 100 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 Is 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:

Normal 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 MEDICAL DEVICES REPERTOIRE:

CND: **A060399**

RDM: **1228508**

● UNIT OF SALE:

Carton with **100 pieces**.

● GTIN-UDI:

PRODUCT CODE	SINGLE PRODUCT	BOX	CARTON
MED50L	05060278508566	25060278508560	45060278508564
MED100L	05060278508535	25060278508539	45060278508533
MED250L	05060278508542	25060278508546	45060278508540
MED500L	05060278508559	25060278508553	45060278508557
MED1000L	05056115403569	25056115403563	45056115403567



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TECHNICAL DATA SHEET



REV.	CHANGES	ISSUED	VERIFIED AND APPROVED	DATE
00	First issue – English language	E. Benassi	D. Bosetti	01/09/2016
01	Data sheet and drawing revision and RDM number update	E. Benassi	D. Bosetti	12/10/2017
02	Drawing and Product Composition update	E. Benassi	D. Bosetti	06/04/2018
03	MED1000L item code added	E. Benassi	D. Bosetti	28/11/2018
04	Packaging updated	E. Benassi	D. Bosetti	30/01/2019
05	Manufacturer legal address and datasheet layout updated	E. Benassi	S. Tralli	19/03/2021
06	Datasheet layout updated	E. Benassi	S. Tralli	30/11/2021