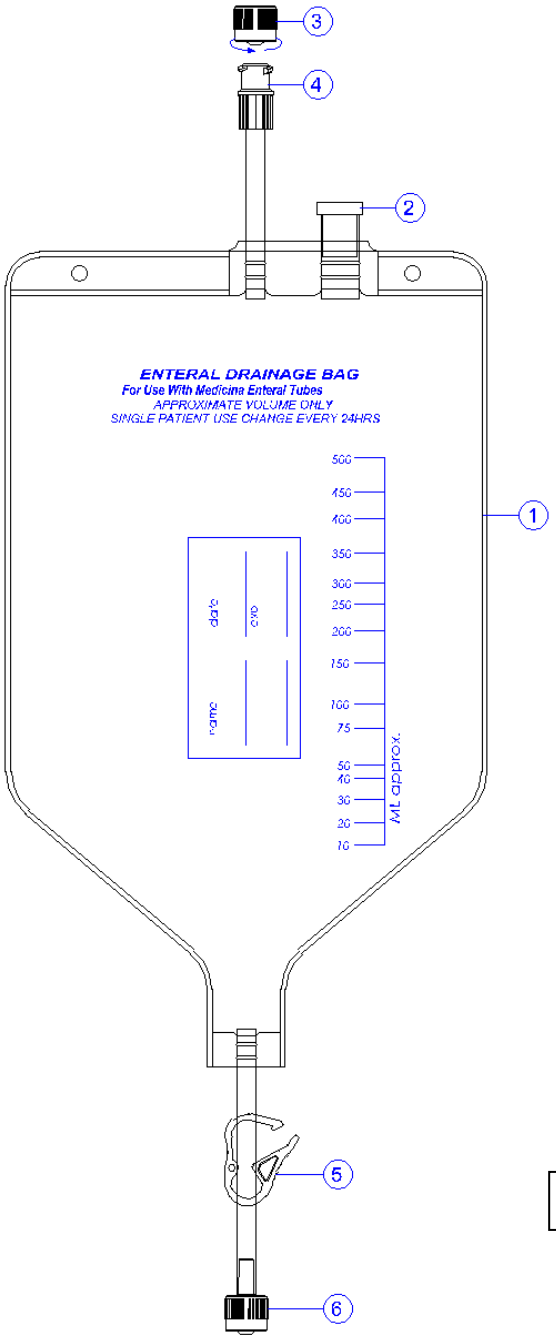
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# SCHEDA TECNICA PRODOTTO
# *Product Technical Data Sheet*

MOD. 07 POS. 002
REV.01
DATA 31/01/2023

## DESCRIZIONE / *Description*
## ENFit ENTERAL DRAINAGE BAG




LATEX

**DEHP FREE**

| CODICE / 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 |

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# SCHEDA TECNICA PRODOTTO
# *Product Technical Data Sheet*



## COMPOSIZIONE PRODOTTO / *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.

## DESTINAZIONE D'USO / *Intended Use*:

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

## CONFEZIONAMENTO / *Packaging*:

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

## CICLO PRODUTTIVO / *Production Process*:

The device is manufactured in accordance with HMC Premedical S.p.A. Quality System and in comply with the requirements of the standard EN ISO 13485.

## CONTROLLI SUL PRODOTTO / *Control On The Product*:

In all stages of processing, according to internal procedures and to sampling plans defined by norm ISO 2859-1.

## CLASSE DI APPARTENENZA / *Classification*:

**Class Is**, according to Rule 5 of Annex VIII to EU Medical Devices Regulation 2017/74.

## STERILIZZAZIONE / *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 manufacturing.
For single-use only and non-re-sterilizable.

## STOCCAGGIO / *Storage*:

Standard storage procedures and conditions.

## SMALTIMENTO / *Disposal*:

The user must follow the legal regulations regarding disposal of hospital waste.

## AVVERTENZE / *Warning*:

The device must be used exclusively by healthcare professionals.

## ISCRIZIONE AL REPERTORIO ITALIANO D.M. / *Registration To Italian M.D. Repertoire*:

CND/EMDN: **A060399**
RDM: **2934828**
GMDN: **62286**

## UNITA' DI VENDITA / *Unit of Sale*:

Carton with **100 pieces**.

## UDI *(Unique Device Identifier)*:

Il sistema di Identificazione UDI presente sull' etichetta è rappresentato con 2 formati / *UDI identification system on the label is represented through 2 formats*:

- Il formato AIDC (Automatic Interface and Data Capture) leggibile da un lettore automatico / *AIDC format (Automatic Interface and Data Capture) readable by an automatic reader*: **DATAMATRIX**
- Il formato HRI è composto da due parti / *HRI format consists of two parts*:
  - **UDI-DI** – parte fissa / fixed part:

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| CODICE/ Code | PRODOTTO SINGOLO / *Single Unit* | BUSTA O SCATOLA / *Inner Pouch or Box* | CARTONE / *Shipping Box* |
|---|---|---|---|
| MED50L | 18053676299505 | 38053676299509 | 58053676299503 |
| MED100L | 18053676299512 | 38053676299516 | 58053676299510 |
| MED250L | 18053676299529 | 38053676299523 | 58053676299527 |
| MED500L | 18053676299536 | 38053676299530 | 58053676299534 |
| MED1000L | 18053676299543 | 38053676299547 | 58053676299541 |

- **UDI-PI** – parte variabile / *variable part*:

**(17)** DATA SCADENZA / *EXPIRY DATE* **(10)** N° LOTTO / *LOT NUMBER*

Andrea Gandini 14 Jan 2026
S. Tralli 14 Jan 2026

| REV. *Rev.* | *MODIFICHE* *Changes* | *EMESSO* *Issued* | *VERIFICATO e APPROVATO* *Verified and Approved* | DATA 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 |
| 07 | Data sheet update for MDD extension | E. Benassi | S. Tralli | 05/06/2024 |
| 08 | First issue MDR; classification and RDM, UDI codes update | A. Gandini | S. Tralli | 16/12/2025 |

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