HMC PREMEDICAL S.p.A.
Via Bosco, 1/3 - 41037 Mirandola (MO) Italy
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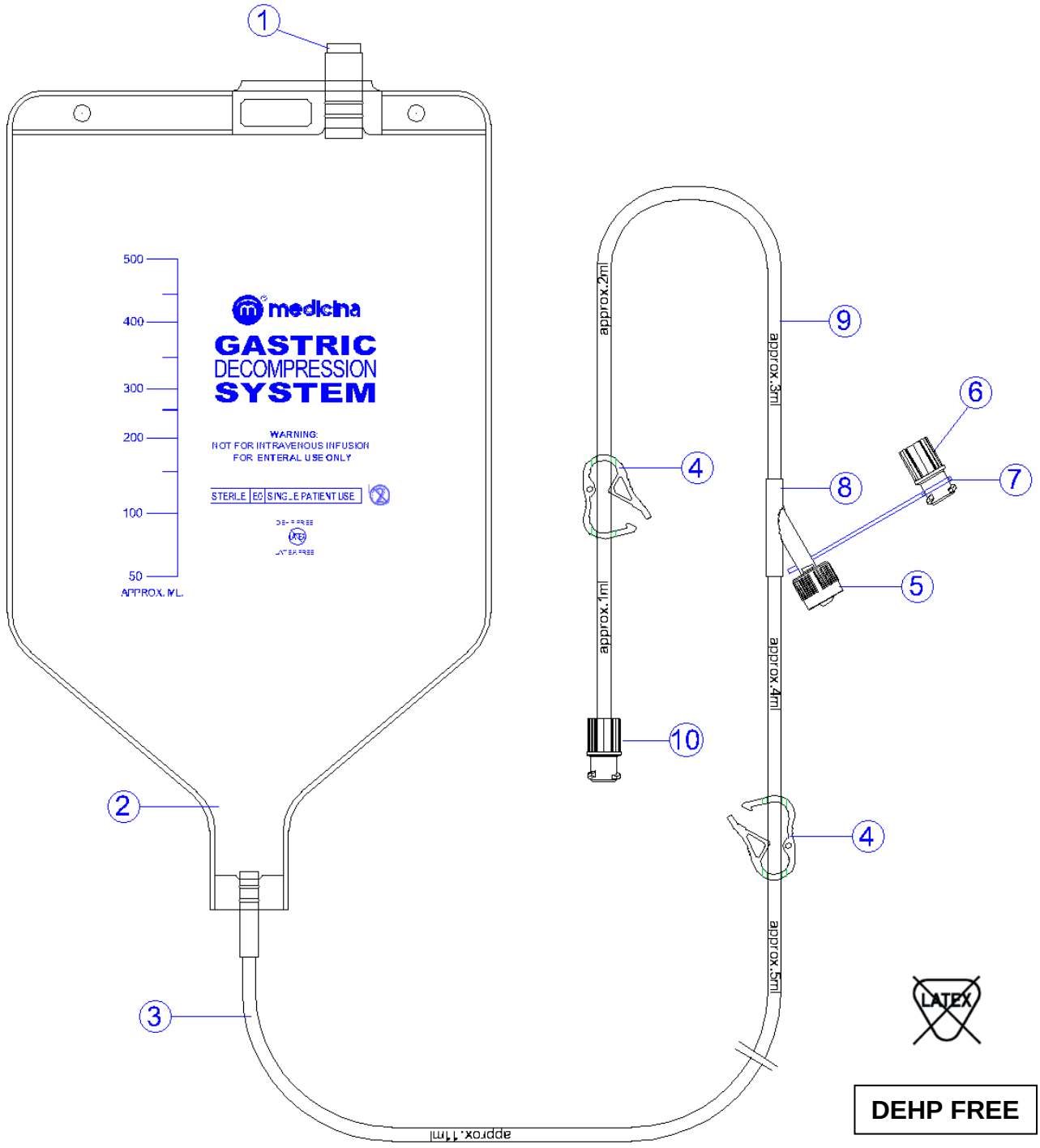
PRODUCT TECHNICAL DATA SHEET

MOD. 07 POS. 002 REV.00
DATA 23/06/2021

CE 0051

DESCRIPTION

ENFit GASTRIC DECOMPRESSION SET



CODE	BAG VOLUME ml	TUBE LENGTH cm	BOX pcs.
EV01L	250	190	30
EV02L	500	190	30
EV03L	1000	190	30

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PRODUCT COMPOSITION:

1. Bushing in white **ABS** with 3 µm hydrophobic filter;
2. Gastric decompression bag in **DEHP FREE PVC**, with variable capacity (see table below);
3. Tube in **DEHP FREE PVC**, Ø 2,7 x 4,15 mm and length 128 cm, with purple marking stripe;
4. Small size clamp in white **PP**;
5. ENFit male connector in purple **ABS**, produced in compliance with ISO 80369-3 norm;
6. ENFit female cap in white **DEHP FREE PVC,** produced in compliance with ISO 80369-3 norm;
7. Strap in purple **DEHP FREE soft PVC**;
8. 3-way " Y " connector with FLL, in clear **ABS**;
9. Tube in **DEHP FREE PVC**, Ø 2,7 x 4,15 mm and length 62 cm, with purple marking stripe;
10. ENFit female connector in purple **ABS**, produced in compliance with ISO 80369-3 norm.

INTENDED USE:

The device is used for pressory compensation and/or stomach decompression during administration of enteral solutions by gravity, in bolus or by means of an enteral feeding pump.
An air vent allows any gas to escape should this be required.

PACKAGING:

Primary packaging: single product in medical grade paper/**PP-PE** film blister.
Secondary packaging: carton with 30 pieces.

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 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 MEDICAL DEVICES REPERTOIRE:

CND: **A030403**
RDM: **1573688**
GMDN: **n/a**

UNIT OF SALE:

Box with **30 pieces**.

UDI:

	SINGLE PRODUCT	BOX
EV01L	05060278508375	25060278508379
EV02L	05060278508382	25060278508386
EV03L	n/a	n/a

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REV.	CHANGES	ISSUED	VERIFIED AND APPROVED	DATE
00	First issue	E. Benassi	D. Bosetti	01/09/2016
01	EV03L 1000 ml bag added	E. Benassi	D. Bosetti	16/02/2017
02	RDM number and Classification update	E. Benassi	D. Bosetti	12/10/2017
03	Manufacturer's legal address update; intended use and layout revision.	E. Benassi	S. Tralli	18/05/2021
04	Data sheet update	E. Benassi	S. Tralli	04/01/2022