HMC PREMEDICAL S.p.A.
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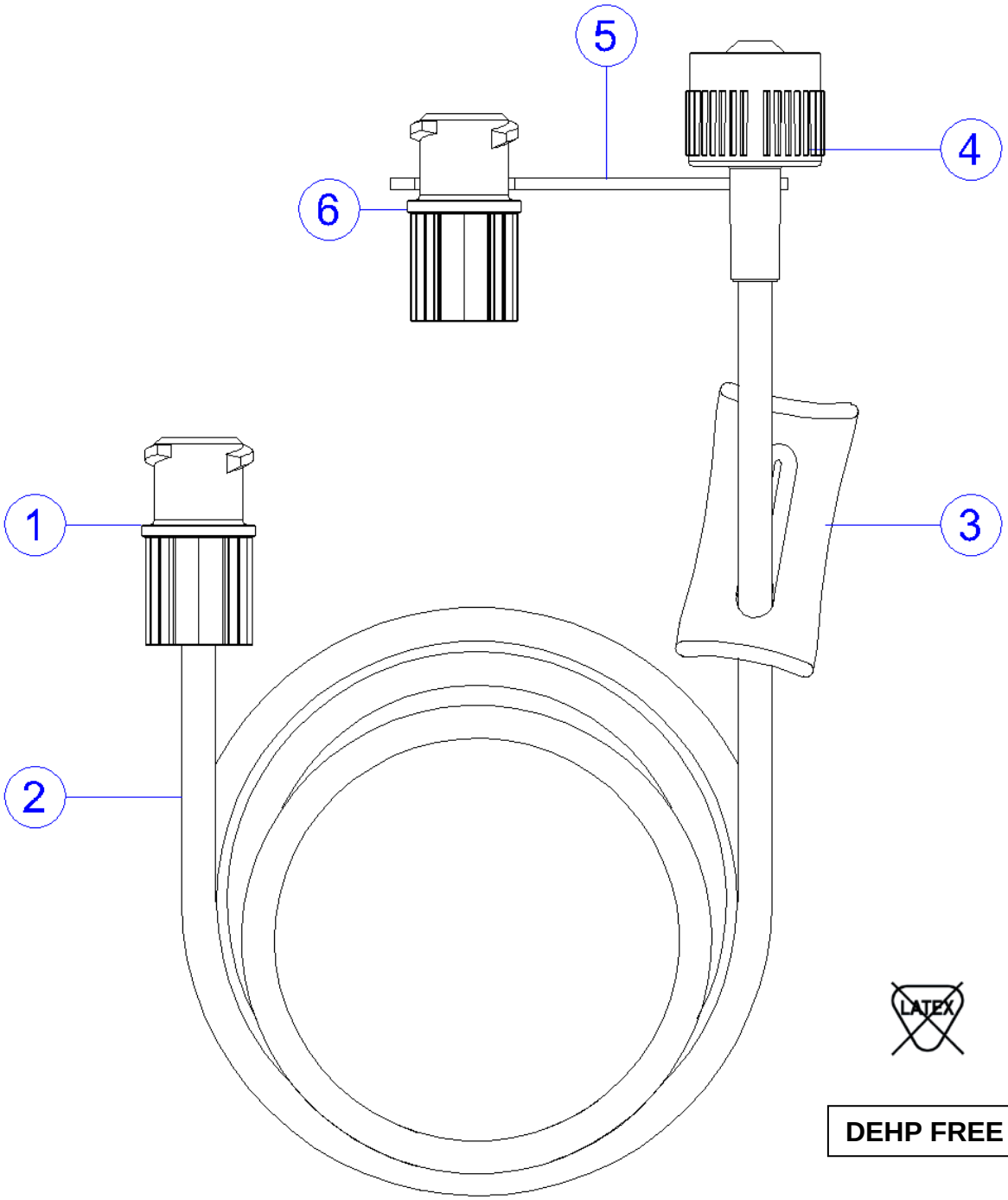
PRODUCT TECHNICAL DATA SHEET

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

CE 0051

DESCRIPTION

ENFit ENTERAL NUTRITION EXTENSION LINE



DEHP FREE

CODE	I.D. – O.D. mm	LENGTH cm	VOLUME ml	BOX pcs.	CARTON pcs.
EP015L	1,3 - 3	15	0,30	50	200
EP075L	1,3 - 3	75	1,10	50	200
EP100L	1,3 - 3	100	1,42	50	200
EP150L	1,3 - 3	150	2,10	50	200

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PRODUCT COMPOSITION:

1. **ENFit** female connector in purple **DEHP FREE PVC,** produced in compliance with UNI CEI EN ISO 80369-3 norm;
2. Tube in clear **DEHP FREE PVC,** I.D. 1,3 mm and O.D. 3 mm, with purple stripe, available in several lengths (see table);
3. Slide clamp in purple **Polyethylene;**
4. **ENFit** male connector in purple **ABS,** produced in compliance with UNI CEI EN ISO 80369-3 norm;
5. White strap in **soft DEHP FREE PVC;**
6. Closed **ENFit** female cap in white **DEHP FREE PVC,** produced in compliance with UNI CEI EN ISO 80369-3 norm.

INTENDED USE:

Extension line for enteral nutrition systems.

PACKAGING:

Primary package: single product in medical grade paper/Film **PP-PE** Blister.
Secondary package: box with 50 pcs; carton with 200 pcs.

PRODUCTION PROCESS:

The device is manufactured in accordance with the Quality System in compliance with the requirements of the standard EN ISO 13485.

CONTROL ON THE PRODUCT:

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

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.

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: **62256**

UNIT OF SALE:

Carton with **200 pieces**.

UDI:

	SINGLE PRODUCT	BOX	CARTON
EP015L	05056115402517	25056115402511	45056115402515
EP075L	05060278508344	25060278508348	45060278508342
EP100L	05056115404085	25056115404089	45056115404083
EP150L	05060278508351	25060278508355	45060278508359

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REV.	CHANGES	ISSUED	VERIFIED AND APPROVED	DATE
00	First issue – English language	E. Benassi	D. Bosetti	14/04/2016
01	Product composition update	E. Benassi	D. Bosetti	03/04/2017
02	Table, Class and RDM number update	E. Benassi	D. Bosetti	02/10/2017
03	EP100L code added; text and layout revision	E. Benassi	S. Tralli	20/01/2020
04	Packaging updated	E. Benassi	S. Tralli	15/04/2020
05	Manufacturer's legal address update	E. Benassi	S. Tralli	18/05/2021
06	Table update	E. Benassi	S. Tralli	26/08/2021
07	Data sheet udpate	E. Benassi	S. Tralli	03/01/2022

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