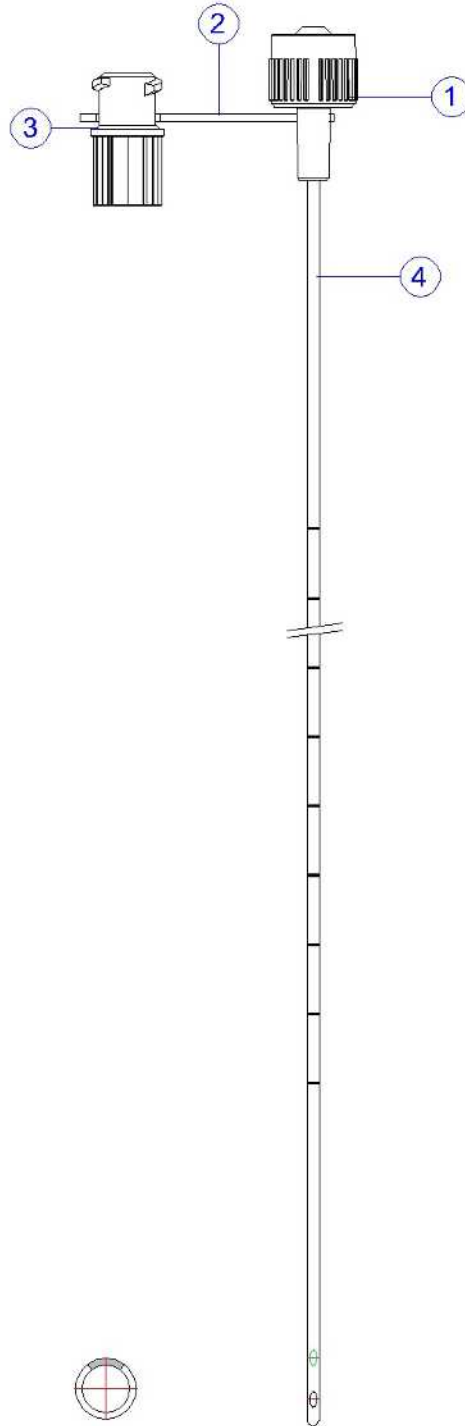


TECHNICAL DATA SHEET

Pediatric ENFit nasogastric tube for enteral nutrition.



DEHP FREE



● PRODUCT COMPOSITION:

1. ENFit male connector in purple **ABS**, produced in compliance with norm ISO 80369-3.
2. Strap in **DEHP FREE PVC** of variable color (see table below).
3. Closed female **ENFit** cap in white **DEHP FREE PVC**, produced in compliance with ISO 80369-3 norm.
4. Graduated feeding tube with variable CHxx and length (see table below), in clear **Polyurethane** with 40% barium sulphate **Radiopaque** white stripe, with two distal eyes.

● INTENDED USE:

Pediatric Nasogastric feeding tube for continuous or intermittent enteral nutrition.

Tubes can also be used on adult patients that require short term treatment (< 30 days).

● PACKAGING:

Single package in double envelope: internal PE bag + Paper/PP-PE film Blister.

Multiple package 50 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.

● WARNINGS:

The device must be used exclusively by healthcare professionals.

● REGISTRATION TO ITALIAN M.D. REPERTOIRE:

CND: **G02020101**

RDM: **1354315**

GMDN: **14221**

TABLE

CODE	Fr	LENGTH cm	DEPTH MARKINGS cm	STRAP COLOR	BOX pcs.
LG4/40	4	40	05 - 30	RED	50
LG4/50	4	50	05 - 40	RED	50
LG4/80	4	80	05 - 70	RED	50
LG4/90 *	4	90	05 - 80	RED	50
LG4/120 *	4	120	05 - 110	RED	50
LG4/125 *	4	125	05 - 115	RED	50
LG4/160 *	4	160	05 - 120	RED	50
LG5/40	5	40	05 - 30	GREY	50
LG5/50	5	50	05 - 40	GREY	50
LG5/80	5	80	05 - 70	GREY	50
LG6/40	6	40	05 - 30	LIGHT GREEN	50
LG6/50	6	50	05 - 40	LIGHT GREEN	50
LG6/80	6	80	05 - 70	LIGHT GREEN	50
LG6/90 *	6	90	05 - 80	LIGHT GREEN	50
LG6/120	6	120	05 - 110	LIGHT GREEN	50
LG6/160 *	6	160	05 - 120	LIGHT GREEN	50
LG8/40	8	40	05 - 30	BLUE	50
LG8/50	8	50	05 - 40	BLUE	50
LG8/80	8	80	05 - 70	BLUE	50
LG8/90 *	8	90	05 - 80	BLUE	50
LG8/120	8	120	05 - 110	BLUE	50
LG8/160 *	8	160	05 - 120	BLUE	50
LG10/50 *	10	50	05 - 40	BLACK	50
LG10/80	10	80	05 - 70	BLACK	50
LG10/120	10	120	05 - 110	BLACK	50
LG10/160 *	10	160	05 - 120	BLACK	50
LG12/80	12	80	05 - 70	WHITE	50
LG12/120	12	120	05 - 110	WHITE	50
LG14/80	14	80	05 - 70	DARK GREEN	50
LG14/120 *	14	120	05 - 110	DARK GREEN	50
LG16/120 *	16	120	05 - 110	RED	50
LG18/120 *	18	120	05 - 110	YELLOW	50

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REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue - English language	14/04/2016	E. Benassi	D. Bosetti
01	Modified intended use	06/07/2016	E. Benassi	D. Bosetti
02	Table update; new codes added and revised markings.	08/03/2017	E. Benassi	D. Bosetti
03	Data sheet revision	10/11/2017	E. Benassi	D. Bosetti
04	LG16/120 and LG18/120 item codes added	05/04/2018	E. Benassi	D. Bosetti
05	GDMN number added	05/07/2019	E. Benassi	E. Benassi