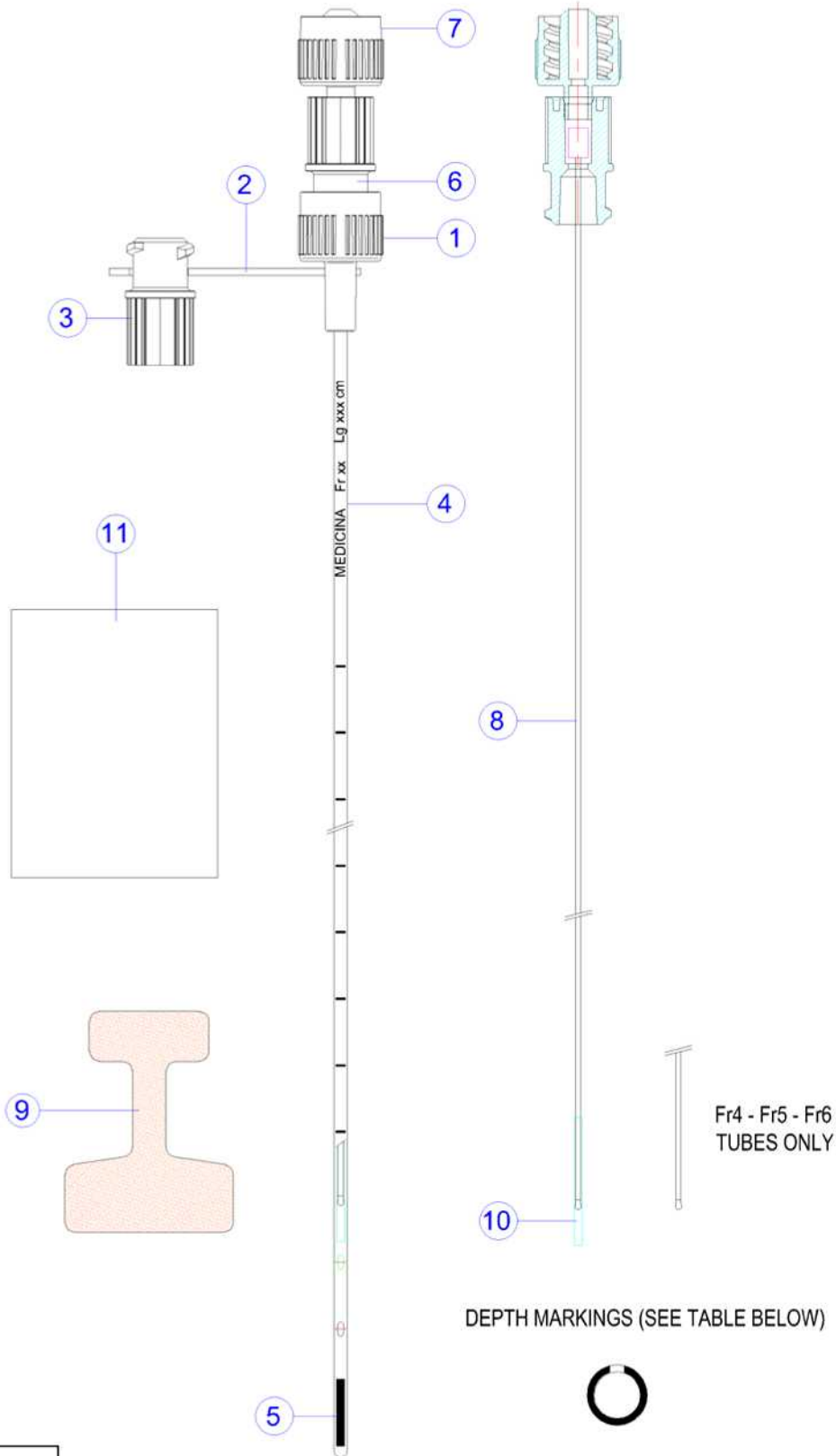


TECHNICAL DATA SHEET

ENFit polyurethane nasogastric feeding tubes with guidewire



DEPTH MARKINGS (SEE TABLE BELOW)

~~LATEX~~
DEHP FREE

● PRODUCT COMPOSITION:

1. ENFit male connector in purple **ABS**, produced in compliance with ISO 80369-3 norm;
2. Strap in **DEHP FREE PVC**;
3. ENFit closed cap in white **DEHP FREE PVC**, produced in compliance with ISO 80369-3 norm;
4. Tube in **Radio-opaque Polyurethane** (40% barium sulphate) with clear stripe, variable Fr and length (see table below) and two distal eyes;
5. Solid cord tube in **Radio-opaque Polyurethane**;
6. ENFit male connector in white **ABS**, produced in compliance with ISO 80369-3 norm;
7. ENFit female connector in white **DEHP FREE PVC**, produced in compliance with ISO 80369-3 norm;
8. Guidewire in **Stainless Steel**;
9. Nasal plaster;
10. Guide end tube in blue **Radio-opaque Polyurethane** (not present on 4 Fr, 5 Fr and 6 Fr tubes);
11. Data registration label.

● INTENDED USE:

These tubes are designed for continuous or intermittent nasogastric enteral feeding, for neonatal, paediatric and adult patients. They can be used to feed, flush and deliver medicines, and to aspirate enteral contents to confirm correct position. The devices are suitable for long term use (>30 days) and are tested for use up to 90 days.

● PACKAGING:

Device is wrapped in a microperforated protective pouch in **Polyethylene** which allows the passage of sterilization gas. Primary packaging: laquered grid paper/PP-PE film Blister.

Secondary packaging: inner box in **pasteboard**, with 25 pcs.; outer box in **double corrugated cardboard**, 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 IIb 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 M.D. REPERTOIRE:

CND: **G02020101**

RDM: **1967644**

GMDN: **14221**

TABLE

CODE	Fr	LENGTH cm	DEPTH MARKINGS cm	BOX pcs.	CARTON pcs.
NGP4/120L	4	120	5 - 110	25	100
NGP5/55L	5	55	5 - 45	25	100
NGP6/55L	6	55	5 - 45	25	100
NGP6/75L	6	75	5 - 65	25	100
NGP6/85L	6	85	5 - 75	25	100
NGP6/120L	6	120	5 - 110	25	100
NGP8/55L	8	55	5 - 45	25	100
NGP8/75L	8	75	5 - 65	25	100
NGP8/85L	8	85	5 - 75	25	100
NGP8/120L	8	120	5 - 110	25	100
NGP10/85L	10	85	5 - 75	25	100
NGP10/120L	10	120	5 - 110	25	100
NGP12/85L	12	85	5 - 75	25	100
NGP12/100L	12	100	5 - 90	25	100
NGP12/120L	12	120	5 - 110	25	100
NGP14/85L	14	85	5 - 75	25	100
NGP14/100L	14	100	5 - 90	25	100
NGP14/120L	14	120	5 - 110	25	100
NGP16/120L	16	120	5 - 110	25	100
NGP18/120L	18	120	5 - 110	25	100

REV. Rev.	MODIFICHE Changes	DATA Date	EMESSO Issued	VERIFICATO e APPROVATO Verified and Approved
00	First issue – English language	27/06/2016	E. Benassi	D. Bosetti
01	Table updated	29/08/2016	E. Benassi	D. Bosetti
02	Table update; new code added and revised markings.	08/03/2017	E. Benassi	D. Bosetti
03	Item code NGP16/120L added.	10/10/2017	E. Benassi	D. Bosetti
04	Item code NGP6/120L added.	05/04/2018	E. Benassi	D. Bosetti
05	Item code NGP4/120L added.	20/11/2018	E. Benassi	D. Bosetti
06	pH Strip removed; packaging updated.	27/03/2019	E. Benassi	D. Bosetti
07	GMDN number added	05/07/2019	E. Benassi	D. Bosetti
08	Drawing updated	11/11/2019	C. Ferrari	E. Benassi
09	Data sheet revision; classification updated to IIb; RDM number updated	22/05/2020	E. Benassi	S. Tralli
10	RDM updated	24/06/2020	E. Benassi	S. Tralli
11	Packaging update	21/12/2020	E. Benassi	S. Tralli
12	Deleted code NGP5/50L	10/02/2021	E. Benassi	S. Tralli