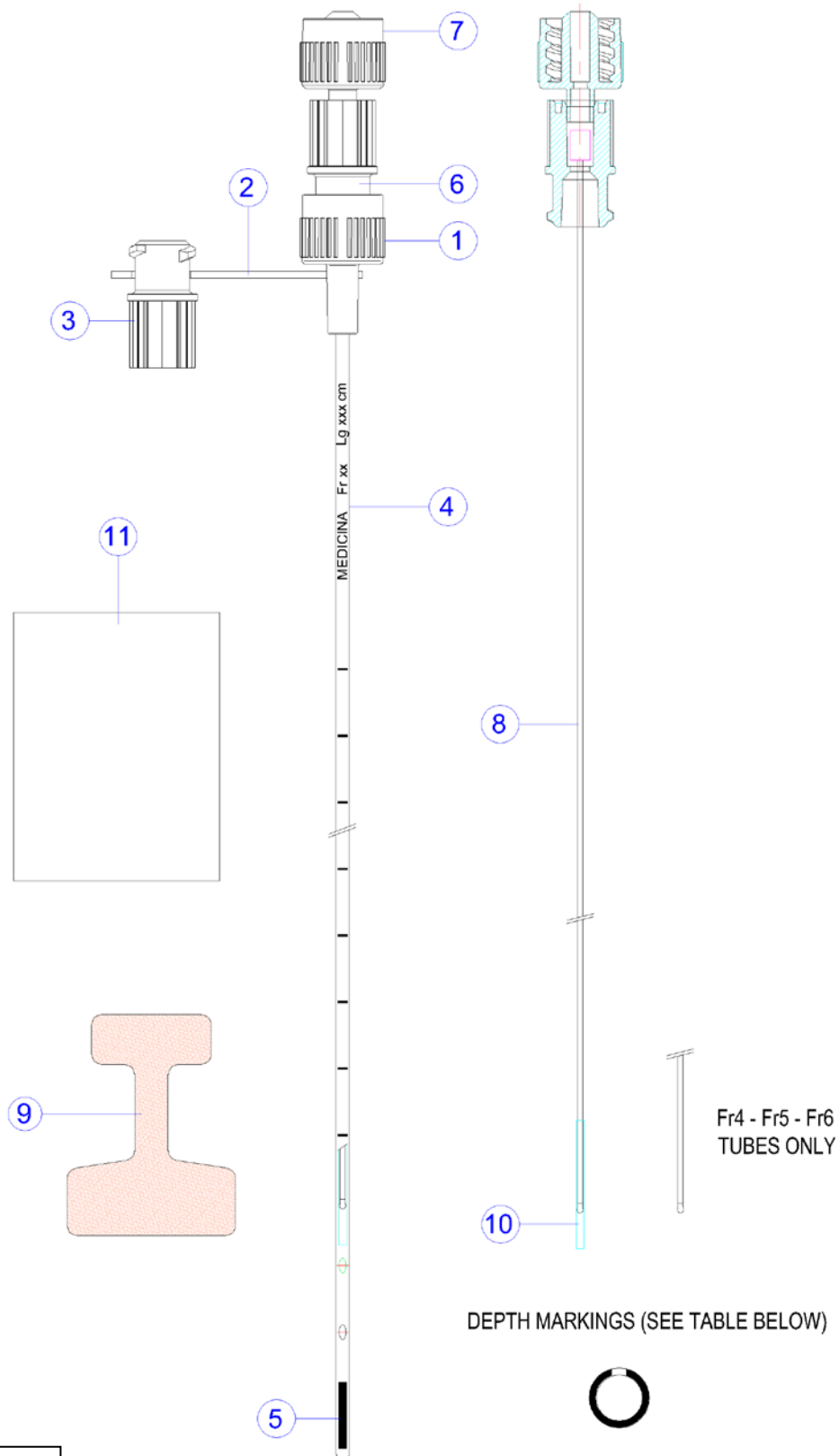


PRODUCT TECHNICAL DATA SHEET

DESCRIPTION

ENFit polyurethane nasogastric feeding tubes with guidewire



PRODUCT TECHNICAL DATA SHEET

TABLE 1

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

● 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.

PRODUCT TECHNICAL DATA SHEET

● PACKAGING:

Primary packaging: microperforated protective pouch in **PE** which allows the passage of sterilization gas + 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 MEDICAL DEVICES REPERTOIRE:

CND: **G02020101**

RDM: **1967644**

GMDN: **14221**

● UNIT OF SALE:

Carton with **100 pieces**.

● UDI:

See **UDI TABLE** for details.

PRODUCT TECHNICAL DATA SHEET

UDI TABLE

	SINGLE PRODUCT	BOX	CARTON
NGP4/120L	05056115402937	25056115402931	45056115402935
NGP5/55L	05056115403781	25056115403785	45056115403789
NGP6/55L	05060278508641	25060278508645	45060278508649
NGP6/75L	05060278508658	25060278508652	45060278508656
NGP6/85L	05060278508665	25060278508669	45060278508663
NGP6/120L	05056115402944	25056115402948	45056115402942
NGP8/55L	05060278508689	25060278508683	45060278508687
NGP8/75L	05060278508696	25060278508690	45060278508694
NGP8/85L	05060278508702	25060278508706	45060278508700
NGP8/120L	05060278508672	25060278508676	45060278508670
NGP10/85L	05060278508634	25060278508638	45060278508632
NGP10/120L	05060278508627	25060278508621	45060278508625
NGP12/85L	05056115400612	25056115400616	45056115400610
NGP12/100L	05060278509280	25060278509284	45060278509288
NGP12/120L	05060278509594	25060278509598	45060278509592
NGP14/85L	05056115400629	25056115400623	45056115400627
NGP14/100L	05056115403897	25056115403891	45056115403895
NGP14/120L	05056115400636	25056115400630	45056115400634
NGP16/120L	05056115403019	25056115403013	45056115403017
NGP18/120L	05056115403903	25056115403907	45056115403901

REV.	CHANGES	ISSUED	VERIFIED AND APPROVED	DATE
00	First issue - English language	E. Benassi	D. Bosetti	27/06/2016
01	Table updated	E. Benassi	D. Bosetti	29/08/2016
02	Table update; new code added and revised markings.	E. Benassi	D. Bosetti	08/03/2017
03	Item code NGP16/120L added.	E. Benassi	D. Bosetti	10/10/2017
04	Item code NGP6/120L added.	E. Benassi	D. Bosetti	05/04/2018
05	Item code NGP4/120L added.	E. Benassi	D. Bosetti	20/11/2018
06	pH Strip removed; packaging updated.	E. Benassi	D. Bosetti	27/03/2019
07	GMDN number added	E. Benassi	D. Bosetti	05/07/2019
08	Drawing updated	C. Ferrari	E. Benassi	11/11/2019
09	Data sheet revision: classification updated to IIb; RDM number updated	E. Benassi	S. Tralli	22/05/2020
10	RDM updated	E. Benassi	S. Tralli	24/06/2020
11	Packaging update	E. Benassi	S. Tralli	21/12/2020
12	Deleted code NGP5/50L	E. Benassi	S. Tralli	10/02/2021
13	Manufacturer's legal address update	E. Benassi	S. Tralli	16/04/2021
14	Data sheet update; UDI table added.	E. Benassi	S. Tralli	05/01/2022