HMC PREMEDICAL S.p.A.
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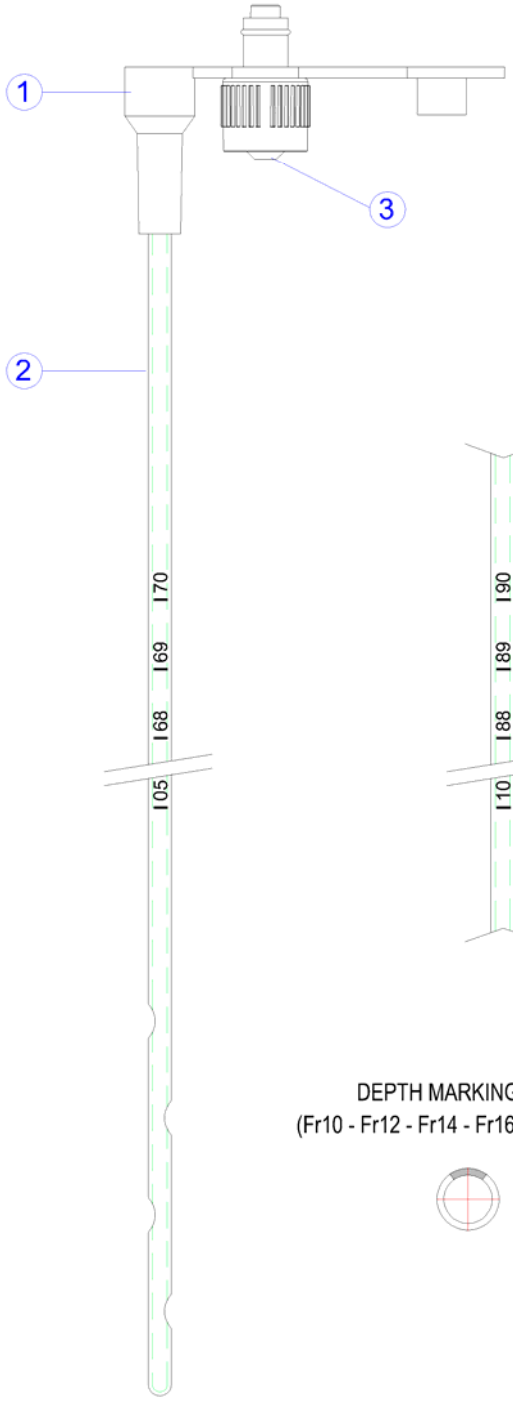
REV. 05 DEL 24/06/2020

CE 0051

TECHNICAL DATA SHEET

ENFit polyurethane nasogastric tubes for feeding/aspiration



LATEX

DEHP FREE

DEPTH MARKINGS 05 - 70
(Fr6 - Fr8)

DEPTH MARKINGS 10 - 90
(Fr10 - Fr12 - Fr14 - Fr16 - Fr18 - Fr20)

CODE	Fr	RYLES CONNECTOR color	LENGTH cm	DEPTH MARKINGS cm	BOX pcs.	CARTON pcs.
RT6/80L	6	LIGHT GREEN	80	5 - 70	25	200
RT8/80L	8	LIGHT BLUE	80	5 - 70	25	200
RT10/100L	10	BLACK	100	10 - 90	25	200
RT12/100L	12	WHITE	100	10 - 90	25	100
RT14/100L	14	DARK GREEN	100	10 - 90	25	100
RT16/100L	16	ORANGE	100	10 - 90	25	100
RT18/100L	18	RED	100	10 - 90	25	100
RT20/100L	20	YELLOW	100	10 - 90	25	100

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PRODUCT COMPOSITION:

1. "Ryles" type connector in **Polyurethane,** differently colored according to tube Fr (see table);
2. Feeding tube in clear **Polyurethane** with white **radio-opaque** stripe (40% barium sulphate) and depth markings, available in several Fr and lengths (see table);
3. ENFit male connector in purple **ABS,** produced in compliance with norm ISO 80369-3.

INTENDED USE:

These tubes are designed for continuous or intermittent nasogastric aspiration for children and adult patients. They can also be used to deliver feeding or medicines, flush, and to aspirate enteral contents to confirm correct position.
To deliver feeding or medicines, the Ryles connector ① can be capped off with the attached ENFit connector ③, to allow the connection of compatible enteral feeding devices; to revert back to aspiration, remove the ENFit connector from the Ryles connector. The devices are suitable for long term use (>30 days) and are tested for use up to 90 days.

PACKAGING:

Primary packaging: single product double packed in internal PE bag + medical paper/PP-PE film Blister.
Secondary packaging: see table.

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: **1967635**
GMDN: **14221**

REV. *Rev.*	***MODIFICHE*** *Changes*	**DATA** *Date*	**EMESSO** *Issued*	***VERIFICATO e APPROVATO*** *Verified and Approved*
00	First issue – English language	06/05/2016	E. Benassi	D. Bosetti
01	Modified Intended Use	06/07/2016	E. Benassi	D. Bosetti
02	Table update; revised depth markings.	08/03/2017	E. Benassi	D. Bosetti
03	Minor modification to text and graphics; packaging updated	28/03/2019	E. Benassi	E. Benassi
04	Layout and text update; GMDN added; classification updated to IIb	22/05/2020	E. Benassi	S. Tralli
05	RDM update	24/06/2020	E. Benassi	S. Tralli