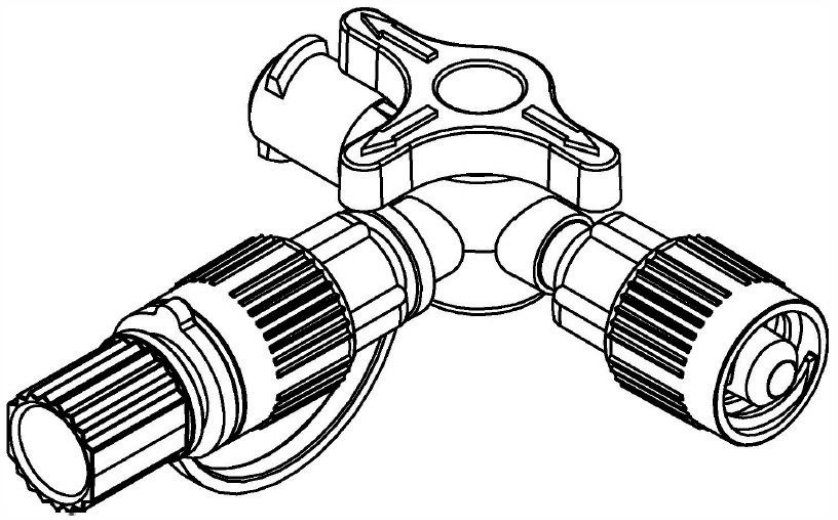
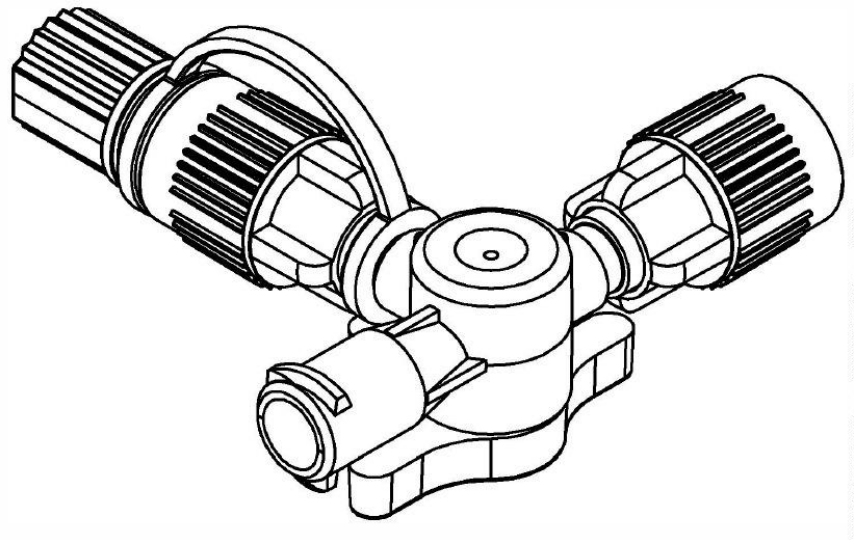
HMC PREMEDICAL SPA
Via Tonino Morandi, 16 - 41037 MIRANDOLA (MO) ITALY Tel. 0535 22704 - Fax. 0535 609546 info@hmcgroup.it

TECHNICAL DATA SHEET

ENFit 4-way stopcock





CODE	BOX pcs.	CARTON pcs.
SA03L	50	200

DEHP FREE

LATEX

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PRODUCT COMPOSITION:

3 way ENFit stopcock with two male rotating connectors and one female connector, all compliant with ISO 80369-3 standard. The materials used to produce the device are as follows:

- Stopcock body and rotating sleeves in **Polycarbonate;**
- ENFit female cap in white **Rigid PVC;**
- Fluid diverter (360° rotation) in **Polyethylene;**
- Strap in white **Soft PVC**.

INTENDED USE:

The device is designed to connect multiple ENFit devices (such as feeding tubes, bags, syringes, extension tubes, accessories…) during enteral feeding procedures. The 360° rotation allows for maximum flexibility, with four possible positions of the fluid diverter.

PACKAGING:

Single packaging in medical paper/PE – PP blister.
Multiple package: 50 pcs. per box; 200 pcs. per carton.

PRODUCTION PROCESS:

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

CONTROL ON THE PRODUCT:

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

CLASSIFICATION:

Classe 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 legal regulations regarding disposal of hospital waste.

WARNINGS:

The device must be used exclusively by healthcare professionals.

REGISTRATION TO ITALIAN M.D. REGISTER:

NR. CND: **A0880** – NR. RDM: **1572532**

REV. *Rev.*	***MODIFICHE*** *Changes*	**DATA** *Date*	**EMESSO** *Issued*	***VERIFICATO e APPROVATO*** *Verified and Approved*
00	First Issue – English language	27/11/2018	E. Benassi	D. Bosetti