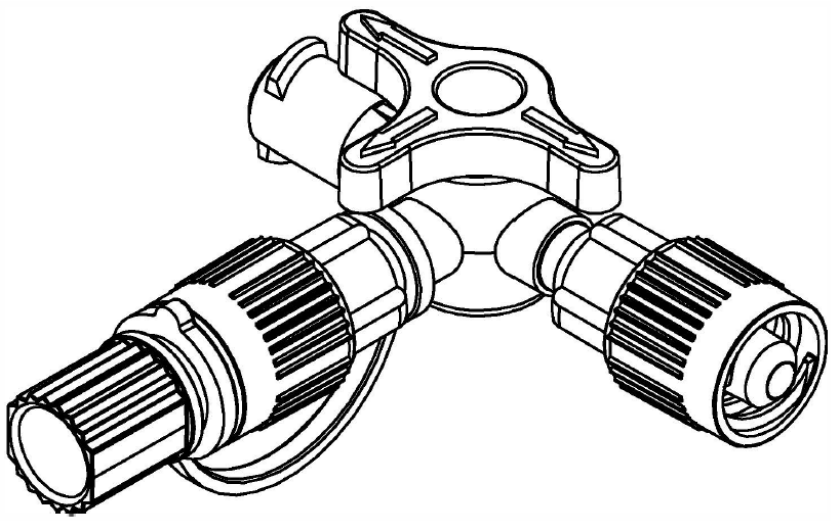
HMC PREMEDICAL S.p.A.
Via Bosco, 1/3 - 41037 Mirandola (MO) Italy
TEL. +39 0535 22704 - FAX. +39 0535 609546
info@hmcgroup.it

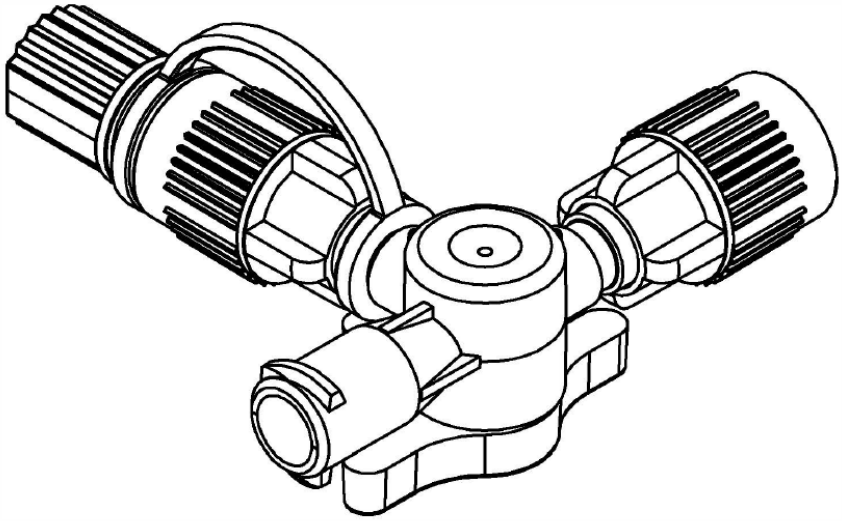
PRODUCT TECHNICAL DATA SHEET

CE 0051

DESCRIPTION

ENFit 4-way stopcock with cap





CODE	BOX pcs.	CARTON pcs.
SA03L	50	200

DEHP FREE

LATEX



IT IS FORBIDDEN THE REPRODUCTION WITHOUT WRITTEN PERMISSION OF HMC GROUP

HMC PREMEDICAL S.p.A.
Via Bosco, 1/3 - 41037 Mirandola (MO) Italy
TEL. +39 0535 22704 - FAX. +39 0535 609546
info@hmcgroup.it

PRODUCT TECHNICAL DATA SHEET

MOD. 07 POS. 002 REV.00
DATA 23/06/2021

CE 0051

PRODUCT COMPOSITION:

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

- Stopcock body and rotating sleeves in **Polycarbonate;**
- ENFit female cap in white **Rigid DEHP FREE PVC;**
- Fluid diverter (360° rotation) in **Polyethylene;**
- Strap in white **Soft DEHP FREE 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 grade paper/**PE–PP** film 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 and 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 MEDICAL DEVICES REGISTER:

CND: **A0880**
RDM: **1572532**
GMDN: **n/a**

UNIT OF SALE:

Carton with **200 pieces**.

UDI:

Single product: **05056115403545**
Box: **25056115403549**
Carton: **45056115403543**

REV.	CHANGES	ISSUED	VERIFIED AND APPROVED	DATE
00	First Issue – English language	E. Benassi	D. Bosetti	27/11/2018
01	Data sheet udpate	E. Benassi	S. Tralli	09/01/2020
02	Update of Legal manufacturer's address	E. Benassi	S. Tralli	26/08/2021
03	Data sheet update	E. Benassi	S. Tralli	10/01/2022

IT IS FORBIDDEN THE REPRODUCTION WITHOUT WRITTEN PERMISSION OF HMC GROUP