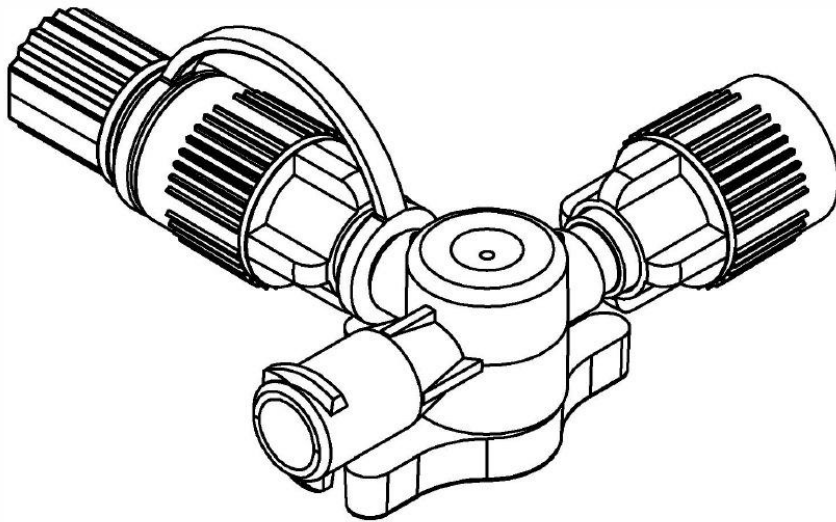
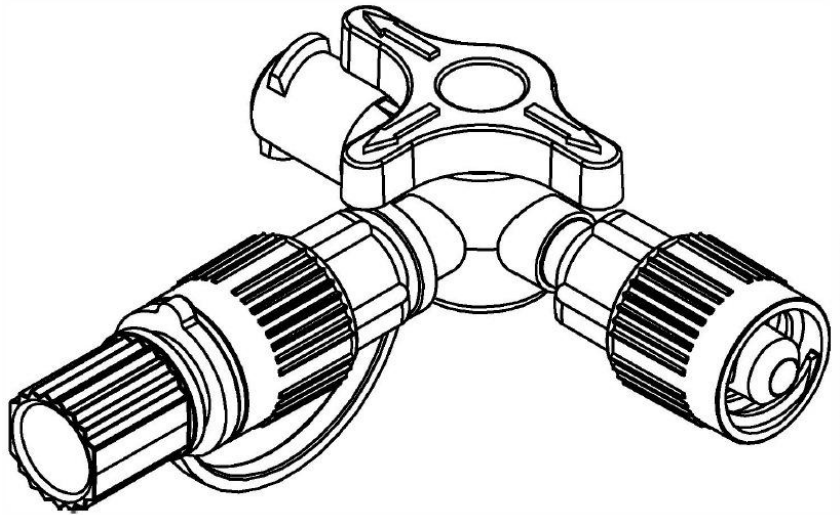


HMC PREMEDICAL SPA

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**

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