

**1. PRODUCT: 3-WAY STOPCOCK / 3-WAY STOPCOCK WITH TUBING**

- CLINI 3-WAY RED (*lipid resistant*) ref: CPHF40017 (MF000A)
- CLINI 3-WAY BLUE (*lipid resistant*) ref: CPHF40017 (MF000A)
- CLINI 3-WAY + 10cm tubing (*DEHP-FREE*) ref: CPHF40017-10DF (EFB004CA010)

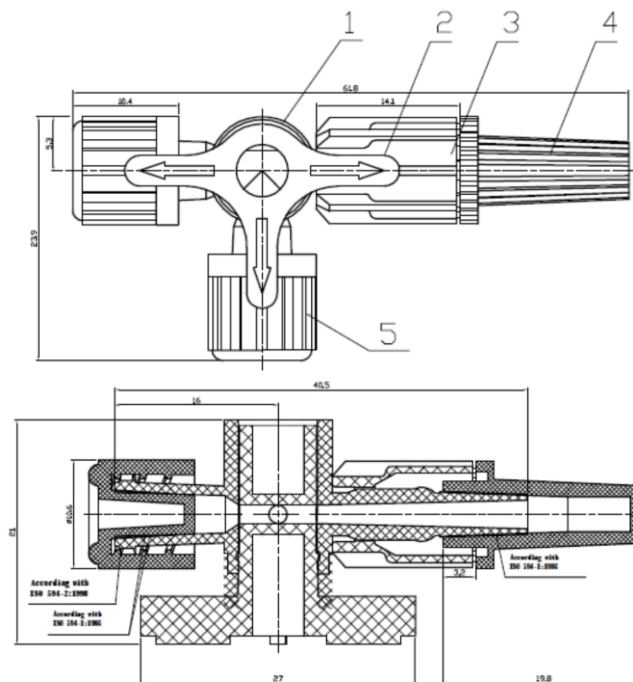
**2. PURPOSE:**

Turning plug that controls the flow of fluid from a container through a tube. A three-way stopcock can be used on IV tubing to turn off one solution and turn on another.

Connection: Luer Lock positive & Luer Lock negative (male & female)

Clinipharma s.r.o. declares that the goods are manufactured in conformity to European medical devices directive **Class IIa, Annex 9, Rule 2** acc. 93/42/EEC including 2007/47/EEC.

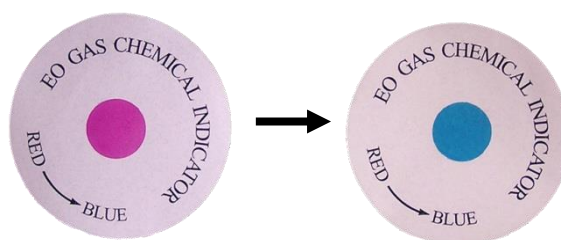
Product is marked CE mark.

**3. DRAWING:**

**4. COMPONENTS:**

No.	Part	Material
1	Valve body	PC / Rx1805
2	Valve core	PE
3	Luer-Lock connector	PC
4	Protective cap	PP
5	Luer-Lock connector	PP

## 5. TECHNICAL SPECIFICATION:

- 3-way stopcock is manufactured in the conditions that minimize particulate contamination. All the surfaces of parts accommodating fluid are smooth and clean. Production process is running in clean rooms ISO class 8.
- 3-way stopcock in unit packages shall be sterile, pyrogen-free and non-toxic for the period of at least 5 years, provided the conditions of transport and storage.
- **Connection:** Luer Lock positive & Luer Lock negative (male & female)
- **Printed data on layout:** The ink used shall be resistant to water to withstand the conditions of sterilization by ethylene oxide gas. The main data are:
  - LOT: unique identification number
  - EXPIRY: date of expiry (yyyy-mm)
  - MFG.DATE: manufacturing date
  - Symbol: Sterile EO
  - REF: reference number
  - Symbol: For single use
  - name and address of manufacturer
  - CE mark
  - storage and transport data
  - Other data and data according customer request



Indicator of EO sterilization used on each

- The product is tested according ISO 594-1 and ISO 594-2:
  - Test for particulate contamination
  - Testing of male and female conical fitting for leakage
  - Sterility tests

## 6. TRANSPORT & STORAGE CONDITION

- The transport of the packed products are allowed to be carried out only in covered, clean and dry means of transport at the temperature within the range from 5°C to +35°C. Take care of the warning data marked on the package during the transport.
- Deliveries are verified after agreement with the customer by means of acceptance sampling according to ISO 2859-1 standard.

## 7. STERILIZATION:

Product is sterilized by ethylene oxide

**8. GUARANTEE:**

Guarantee of sterility is 5 years.

**9. USED STANDARDS:**

MDD 93/42/EEC including revision 2007/47/EEC

ISO 8536-10, EN ISO 11135-1, EN ISO 15223-1, EN ISO 14971, EN ISO 11607-1

**10. PACKAGING DETAILS:**

For unit packaging is used medical grade paper with film, which is suitable for sterilization by EO.

Soft blister	<i>Pcs in blister</i>	<b>1</b>
	<i>Size [mm]</i>	<b>93 x 44</b>
Inner box	<i>Pcs in box</i>	<b>200</b>
	<i>Size [mm]</i>	<b>270x200x180</b>
Shipping carton	<i>Pcs in carton</i>	<b>1 600</b>
	<i>Size [mm]</i>	<b>560x420x380</b>
	<i>Volume [m3]</i>	<b>0,0894</b>
	<i>Weight [kg]</i>	<b>10,5</b>

**11. PHOTO OF PRODUCT:**

Revision: 01/14.11.2022  
00/01.02.2013

