

## DECLARATION OF CONFORMITY

### STERILE MEDICAL DEVICES (PRO-OMNIA LOCK)

The underwrite company **Pro-Active S.r.l.** with corporate domicile in viale del Commercio, 12 - 45100 Rovigo (RO) Italy, manufacturer of sterile medical devices, named and identified by the code (Annex I.) and his worldwide distributor as licence holder these products CliniPharma s.r.o., address Viklefova street 1795/10, 130 00 Prague, Czech Republic, ID: 246 72 769

## DECLARE

the above-mentioned products are in compliance with all the applicable dispositions of Directive 93/42/EEC (as amended by 2007/47/CE Directive) on Medical Devices and with essential requirements of annex I of the same Directive

To that end Pro-Active S.r.l. declare, under its own responsibility, that:

- the above-mentioned products are classifiable in the class risk Is;
- the above-mentioned products are not measure instruments;
- the above-mentioned products are no destined to clinical investigation;
- the above-mentioned products are merchandised in sterile packaging;
- the certificate that certifies the compliance of these devices with Directive 93/42/EEC (as amended by 2007/47/CE Directive) is the number MED004456-00 issued by ICIM (CE 0425), date of issue: 25/05/2021 valid till: 26/05/2024

In the end, Pro-Active S.r.l. declare that it holds the documentation relating to annex VII of 93/42/EEC Directive as amended of its technical file about products for five years beginning from the date of the last piece produced.



Clinipharma s.r.o.

ProActive S.R.L.



### CLINIPHARMA s.r.o.

Viklefova 1795/10 – 13000 PRAGUE / CZECH REPUBLIC

E-mail: [info@clinipharma.cz](mailto:info@clinipharma.cz)

ID company: 246 72 769 ID VAT: CZ 246 72 769

Bank: CSOB Prague - IBAN: CZ45 0300 0000 0002 5414 6747 - BIC: CEKOCZPP

### PRO-ACTIVE S.R.L.

V.le del Commercio, 12 – 45100 ROVIGO / ITALY – Tel. +39.0425.491087; Fax +39.0425.490101

E-mail: [info@proactivesrl.it](mailto:info@proactivesrl.it) - Web site: [www.proactivesrl.it](http://www.proactivesrl.it)

Partita IVA/VAT: IT01248310292 – REA 139577

Banca/Bank: Cassa di Risparmio del Veneto - IBAN: IT 33 G 06225 12203 100000001146 - BIC: IBSP IT 2P



### ANNEX I

PRO-OMNIA LOCK			
Product name	Colour	ProActive REF	Clinipharma REF
PRO-OMNIA LOCK withdrawal cannula	GREEN	M1609	CPHF-CS01
PRO-OMNIA LOCK withdrawal cannula	BLUE	M1610	CPHF-CS05
PRO-OMNIA LOCK withdrawal cannula	RED	M1611	CPHF-CS10
TRANSFER NEEDLE		M1608	CPHF40030
COMBI STOPPER	RED	M1603	CPHF-WYJ32
COMBI STOPPER	BLUE	M1602	CPHF-WYJ32B
COMBI STOPPER	WHITE	M1605	CPHF-WYJ32W
PRO-OMNIA LOCK withdrawal cannula with needle free port	GREEN		CPHF-CS01NF
PRO-OMNIA LOCK withdrawal cannula with needle free port	BLUE		CPHF-CS05NF
PRO-OMNIA LOCK withdrawal cannula with needle free port	RED		CPHF-CS10NF



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