

DECLARATION OF CONFORMITY

PRO-OMNIA LOCK

The underwrite company **Pro-Active S.r.l.** with corporate domicile in viale del Commercio, 12 - 45100 Rovigo (RO), manufacturer of device for infusion and transfusion - accessories, named PRO-OMNIA LOCK and identified by the code of annex I to this declaration

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 not measure instruments;
- the above mentioned products are no destined to clinical investigation;
- the above mentioned products are merchandised in sterile packaging;
- the above mentioned do not contain drug substances or elements of animal origin;
- the above mentioned are latex-free;
- the quality management system is in compliance with ISO 13485:2016 standard
- the certificate that certify the compliance of these devices with Directive 93/42/EEC (as amended by 2007/47/CE Directive) is the number 0425-MED-004456-00 issued by ICIM S.p.a. (CE 0425), Piazza Don Enrico Mapelli 75, 20099 Sesto San Giovanni (MI), Italy. Date of issue : 25/05/2021 valid till : 26/05/2024

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

Rovigo, 21/08/2023

PROACTIVE S.r.l.
Viale del Commercio, 12
45100 ROVIGO - ITALY
Pro-Active S.r.l.

Quality Manager

Fabio Mazzocchi

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PRO-ACTIVE S.R.L.

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

ANNEX TO DECLARATION OF CONFORMITY

MODEL	REF	Secondary REF (Distributor ID)	Description	Class Risk
PRO-OMNIA LOCK	M1609	CPHF-CS01	withdrawal cannula – green cap	Is
PRO-OMNIA LOCK	M1610	CPHF-CS05	withdrawal cannula – blue cap	Is
PRO-OMNIA LOCK	M1611	CPHF-CS10	withdrawal cannula –red cap	Is
PRO-OMNIA LOCK	M1608	CPHF40030	Transfer needle	Is
PRO-OMNIA LOCK	M1603	CPHF-WYJ32	Red combi stopper – male/female LL cap	Is
PRO-OMNIA LOCK	M1602	CPHF-WYJ32B	Blue combi stopper – male/female LL cap	Is
PRO-OMNIA LOCK	M1605	CPHF-WYJ32W	White combi stopper – male/female LL cap	Is
PRO-OMNIA LOCK	M1606	CPHF-WYJ31	Yellow injection cap	Is