

DECLARATION OF CONFORMITY**INFU-PRO**

The underwrite company Pro-Active S.r.l. with corporate domicile in viale del Commercio, 12 - 45100 Rovigo (RO), manufacturer of I.V. giving set, named INFU-PRO 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 not 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 13485:2021 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 INFU-PRO for ten years beginning from the date of the last INFU-PRO piece produced.

Rovigo 31/01/2024,

PROACTIVE S.r.l.

Viale del Commercio, 12

45100 ROVIGO - ITALY

Pro-Active S.r.l.

Quality Manager

Fabio Mazzocchi



PRO-ACTIVE S.R.L.

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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 TO DECLARATION OF CONFORMITY

MODEL	REF	Secondary REF (Distributor ID)	Description	Class Risk
INFU-PRO	I1108FRLLDF/180	CPHF40010-180DF	I.V. giving set in PVC DEHP-FREE – 180 cm long	IIa
INFU-PRO	I1108FRQDF/180	CPHF40010CHV-180DF	I.V. giving set in PVC DEHP-FREE with check valve – 180 cm long	IIa
INFU-PRO	I1108FRLL/150 BE	CPHF40010-BE150DF	I.V. giving set in PVC DEHP-FREE BLUE EYE– 150 cm long	IIa
INFU-PRO	I1108FRLL/150	CPHF40010-S3150	I.V. giving set in PVC – 150 cm long	IIa
INFU-PRO	I0208FRLLDF/150	D1L4005/150	I.V. giving set in PVC DEHP-FREE– 150 cm long	Is
INFU-PRO	I0208FRLLHDF/180	D24005/180	I.V. giving set in PVC DEHP-FREE with airstop, primestop – 180 cm long	Is
INFU-PRO	I0208FRQDF/180	D24005CHV/180	I.V. giving set in PVC DEHP-FREE with airstop, primestop and check valve – 180 cm long	Is

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