

**DECLARATION OF CONFORMITY****TRASFU-PRO**

**The underwrite company Pro-Active S.r.l.** with corporate domicile in viale del Commercio, 12 - 45100 Rovigo (RO), manufacturer of blood giving set, named TRASFU-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 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 TRASFU-PRO for ten years beginning from the date of the last TRASFU-PRO piece produced.

Rovigo 20/10/2023,

**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.**

V.le del Commercio, 12 - 45100 ROVIGO - 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 TO DECLARATION OF CONFORMITY

<b>MODEL</b>	<b>REF</b>	<b>Secondary REF (Distributor ID)</b>	<b>Description</b>	Class Risk
TRASFU-PRO	T0408RLLD/150	CPHF40020DF	UnoHem 150 - PVC DEHP-free blood giving set with non-vented spike	IIa
TRASFU-PRO	T0108RLLD/180	H2L40048/180	DuoHem 150 - PVC DEHP-free blood giving set with non-vented spike and double drip-chamber	IIa

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

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