

DECLARATION OF CONFORMITY**PRO-LONG TUBE**

The underwrite company Pro-Active S.r.l. with corporate domicile in viale del Commercio, 12 - 45100 Rovigo (RO), manufacturer of extension lines, named PRO-LONG TUBE 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-LONG TUBE for ten years beginning from the date of the last PRO-LONG TUBE 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 - Web site: 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

MODEL	REF	Secondary REF (Distributor ID)	Description	Class Risk
PRO-LONG TUBE	EFB036AA010	CPHF40027DF	LS-2 extension line DEHP FREE	IIa
PRO-LONG TUBE	EFE000AA150	CPHF52150	PE Extension line - Ø 1,0 x 2,0 mm - cm 150	IIa
PRO-LONG TUBE	EFE000AA200	CPHF52200	PE Extension line - Ø 1,0 x 2,0 mm - cm 200	IIa
PRO-LONG TUBE	EFB004AA015	CPHF51015DF	PVC DEHP-free Extension line HV 15 (Heidelberger) Ø 3,0 x 4,1 mm - cm 15	IIa
PRO-LONG TUBE	EFB004AA030	CPHF51030DF	PVC DEHP-free Extension line HV 30 (Heidelberger) Ø 3,0 x 4,1 mm - cm 30	IIa
PRO-LONG TUBE	EFB004AA075	CPHF51070DF	PVC DEHP-free Extension line HV 75 (Heidelberger) Ø 3,0 x 4,1 mm - cm 75	IIa
PRO-LONG TUBE	EFB004AA140	CPHF51150DF	PVC DEHP-free Extension line HV 140 (Heidelberger) Ø 3,0 x 4,1 mm - cm 140	IIa
PRO-LONG TUBE	EFB004AA190	CPHF51190DF	PVC DEHP-free Extension line HV 190 (Heidelberger) Ø 3,0 x 4,1 mm - cm 190	IIa
PRO-LONG TUBE	EFB002AA150	CPHF50150DF	PVC DEHP-free PERFUSION line - cm 150	IIa
PRO-LONG TUBE	EFB002AA200	CPHF50200DF	PVC DEHP-free PERFUSION line - cm 200	IIa
PRO-LONG TUBE	EFB002AA300	CPHF50300DF	PVC DEHP-free PERFUSION line - cm 300	IIa
PRO-LONG TUBE	EFB004CA010	CPHF40017-10DF	3-way stopcocks BLUE with PVC DEHP-free extension line Ø 3,0 x 4,1 - cm 10	IIa

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