



DECLARATION OF CONFORMITY

Manufacturer:

Luropas del dottor Molinari & C. Srl
Via Vivaldi 4
24040 Calvenzano (BG) – Italy

We, the manufacturer, herewith declare that the following products:

ITEM CODE	PRODUCT NAME	INDED USE	DEVICE CLASS	CND CODES	BASIC UDI-DI
562BEI	GAMBALETTTO K1 TRAMATO PUNTA APERTA – SIZE 1 GAMBALETTTO K1 TRAMATO PUNTA APERTA – SIZE 2 GAMBALETTTO K1 TRAMATO PUNTA APERTA – SIZE 3 GAMBALETTTO K1 TRAMATO PUNTA APERTA – SIZE 4 GAMBALETTTO K1 TRAMATO PUNTA APERTA – SIZE 5 GAMBALETTTO K1 TRAMATO PUNTA APERTA – SIZE 6	K1 – K2 therapeutic and medical hosiery, open toe. Recommended for the treatment of the venous insufficiency, also chronic, with development of varicose veins, formation of phlebitis, oedema, and varicose ulcers. Efficient in case of thrombophlebitis, postoperative prophylaxis, surgical operations on varicose veins, sclerotherapy and trauma and fractures of the lower limbs.	I, Rule 1 (Annex VIII of MDR2017/745)	M030405	803261520TLUROPAS74
563BEI	CALZA AUTOREG. K1 TRAMATA PUNTA APERTA – SIZE 1 CALZA AUTOREG. K1 TRAMATA PUNTA APERTA – SIZE 2 CALZA AUTOREG. K1 TRAMATA PUNTA APERTA – SIZE 3 CALZA AUTOREG. K1 TRAMATA PUNTA APERTA – SIZE 4 CALZA AUTOREG. K1 TRAMATA PUNTA APERTA – SIZE 5 CALZA AUTOREG. K1 TRAMATA PUNTA APERTA – SIZE 6			M030405	
572BEI	GAMBALETTTO K2 TRAMATO PUNTA APERTA – SIZE 1 GAMBALETTTO K2 TRAMATO PUNTA APERTA – SIZE 2 GAMBALETTTO K2 TRAMATO PUNTA APERTA – SIZE 3 GAMBALETTTO K2 TRAMATO PUNTA APERTA – SIZE 4 GAMBALETTTO K2 TRAMATO PUNTA APERTA – SIZE 5 GAMBALETTTO K2 TRAMATO PUNTA APERTA – SIZE 6			M030405	
573BEI	CALZA AUTOREG. K2 TRAMATA PUNTA APERTA – SIZE 1 CALZA AUTOREG. K2 TRAMATA PUNTA APERTA – SIZE 2 CALZA AUTOREG. K2 TRAMATA PUNTA APERTA – SIZE 3 CALZA AUTOREG. K2 TRAMATA PUNTA APERTA – SIZE 4 CALZA AUTOREG. K2 TRAMATA PUNTA APERTA – SIZE 5 CALZA AUTOREG. K2 TRAMATA PUNTA APERTA – SIZE 6			M030405	

meet the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

Applicable standards:

UNI EN ISO 13485:2016
UNI CEI EN 15223-1:2017
ISO 14971:2019
ISO 10993-1: 2018
ISO 10993-5: 2018

We, the manufacturer, herewith declare under our own responsibility, that our above-mentioned products meet the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Natale Molinari

Stamp and signature

Date: 27/5/2021

Place: Calvenzano (BG), Italy

LUROPAS
del dott. Molinari & C. s.r.l.
Cap. Soc. € 45.000,00 i.v.
Via Vivaldi, 4 - 24040 CALVENZANO (BG)
Tel. 0363 86666 - Fax 0363 85281
Cod. Fisc. e Partita IVA 00683840169