



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
880	THERMOTEX POLSIERA REG. BLU – SIZE 1 THERMOTEX POLSIERA REG. BLU – SIZE 2 THERMOTEX POLSIERA REG. BLU – SIZE 3 THERMOTEX POLSIERA REG. BLU – SIZE 4	elasticised braces for the supporting and the stability of the articulations, preventing and reducing the possibility of lesions. In neoprene sponge, which allows the skin to breathe and allows the internal part to keep the heat generated by the body while in activity. This assures a higher temperature in the interested area and favours the bloodstream contributing to a quicker recovery of potential strains and sprains.	I, Rule 1 (Annex VIII of MDR2017/745)	Y060609	803261520ZLUROPASAN
881	THERMOTEX FASCIA EPICONDILITE REG. BLU – SIZE 1 THERMOTEX FASCIA EPICONDILITE REG. BLU – SIZE 2 THERMOTEX FASCIA EPICONDILITE REG. BLU – SIZE 3 THERMOTEX FASCIA EPICONDILITE REG. BLU – SIZE 4			Y060609	
882	THERMOTEX CAVIGLIERA REG. BLU – SIZE 1 THERMOTEX CAVIGLIERA REG. BLU – SIZE 2 THERMOTEX CAVIGLIERA REG. BLU – SIZE 3 THERMOTEX CAVIGLIERA REG. BLU – SIZE 4			Y061206	
883	THERMOTEX GINOCCHIERA SPECIALE BLU – SIZE 1 THERMOTEX GINOCCHIERA SPECIALE BLU – SIZE 2 THERMOTEX GINOCCHIERA SPECIALE BLU – SIZE 3 THERMOTEX GINOCCHIERA SPECIALE BLU – SIZE 4			Y061209	
884	THERMOTEX GINOCCHIERA FORO REG. BLU – SIZE 1 THERMOTEX GINOCCHIERA FORO REG. BLU – SIZE 2 THERMOTEX GINOCCHIERA FORO REG. BLU – SIZE 3 THERMOTEX GINOCCHIERA FORO REG. BLU – SIZE 4			Y061209	
885	THERMOTEX GINOCCHIERA ROTULEA BLU – SIZE 1 THERMOTEX GINOCCHIERA ROTULEA BLU – SIZE 2 THERMOTEX GINOCCHIERA ROTULEA BLU – SIZE 3 THERMOTEX GINOCCHIERA ROTULEA BLU – SIZE 4			Y061209	
886	PRESSORE ROTULEO REGOLABILE			Y061209	

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: 27/05/2021

Place: Calvenzano (BG), Italy


LUROPAS
del dott. Molinari & C. s.r.l.
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