



# DECLARATION OF CONFORMITY

**Manufacturer:**

Luropas del dottor Molinari &amp; 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
531	CAVIGLIERA POLIESTENSIBILE COTONE – SIZE I CAVIGLIERA POLIESTENSIBILE COTONE – SIZE II CAVIGLIERA POLIESTENSIBILE COTONE – SIZE III CAVIGLIERA POLIESTENSIBILE COTONE – SIZE IV CAVIGLIERA POLIESTENSIBILE COTONE – SIZE V	Elasticized ankle braces with and without stays, for the prevention and care of ankle diseases, for example following traumas, distortions, muscular overload, injuries in sport activities.	I, Rule 1 (Annex VIII of MDR2017/745)	Y061206	803261520FLUROPASWP
534	CAVIGLIERA INCROCIATA COTONE – SIZE I CAVIGLIERA INCROCIATA COTONE – SIZE II CAVIGLIERA INCROCIATA COTONE – SIZE III CAVIGLIERA INCROCIATA COTONE – SIZE IV CAVIGLIERA INCROCIATA COTONE – SIZE V			Y061206	
537	CAVIGLIERA SCUDOTEX SPORTING – SIZE I CAVIGLIERA SCUDOTEX SPORTING – SIZE II CAVIGLIERA SCUDOTEX SPORTING – SIZE III CAVIGLIERA SCUDOTEX SPORTING – SIZE IV CAVIGLIERA SCUDOTEX SPORTING – SIZE V			Y061206	
540	CAVIGLIERA REKORDSAN DYNAMIC – SIZE I CAVIGLIERA REKORDSAN DYNAMIC – SIZE II CAVIGLIERA REKORDSAN DYNAMIC – SIZE III CAVIGLIERA REKORDSAN DYNAMIC – SIZE IV CAVIGLIERA REKORDSAN DYNAMIC – SIZE V			Y061206	
560	CAVIGLIERA ELASTICA A DOPPIA FORZA – SIZE I CAVIGLIERA ELASTICA A DOPPIA FORZA – SIZE II CAVIGLIERA ELASTICA A DOPPIA FORZA – SIZE III CAVIGLIERA ELASTICA A DOPPIA FORZA – SIZE IV CAVIGLIERA ELASTICA A DOPPIA FORZA – SIZE V			Y061206	
561	CAVIGLIERA ELASTICA FORTE – SIZE I CAVIGLIERA ELASTICA FORTE – SIZE II CAVIGLIERA ELASTICA FORTE – SIZE III CAVIGLIERA ELASTICA FORTE – SIZE IV CAVIGLIERA ELASTICA FORTE – SIZE V			Y061206	
538	CAVIGLIERA STECCATA REGOLABILE – SIZE I CAVIGLIERA STECCATA REGOLABILE – SIZE II CAVIGLIERA STECCATA REGOLABILE – SIZE III CAVIGLIERA STECCATA REGOLABILE – SIZE IV			Y061206	
888	CAVIGLIERA AIR BI-VALVA – 1 SIZE FITS FOR ALL			Y061206	

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**Date:** 27/5/2021**Place:** Calvenzano (BG), Italy**Stamp and signature**

**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