



## 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
448	BRACCIALE PALMARE K2 medio – SIZE II BRACCIALE PALMARE K2 medio – SIZE III BRACCIALE PALMARE K2 medio – SIZE IV	Medical medium armband recommended after mastectomy operations and for the treatment of the vein insufficiency of the upper limbs.	I, Rule 1 (Annex VIII of MDR2017/745)	Y061899	803261520ULUROPAS7P
449	BRACCIALE PALMARE K2 lungo – SIZE II BRACCIALE PALMARE K2 lungo – SIZE III BRACCIALE PALMARE K2 lungo – SIZE IV	Medical long armband recommended after mastectomy operations and for the treatment of the vein insufficiency of upper the limbs.		Y061899	

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.  
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