



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
541	POLSINO ELASTICO NATURALE cm 6 – SIZE I POLSINO ELASTICO NATURALE cm 6 – SIZE II POLSINO ELASTICO NATURALE cm 6 – SIZE III POLSINO ELASTICO NATURALE cm 6 – SIZE IV POLSINO ELASTICO NATURALE cm 6 – SIZE V	Elastic protection to support the wrist join.	I, Rule 1 (Annex VIII of MDR2017/ 745)	Y060609	803261520HLUROPASXV
542	POLSINO ELASTICO BIANCO cm 6 – SIZE I POLSINO ELASTICO BIANCO cm 6 – SIZE II POLSINO ELASTICO BIANCO cm 6 – SIZE III POLSINO ELASTICO BIANCO cm 6 – SIZE IV POLSINO ELASTICO BIANCO cm 6 – SIZE V	Elastic protection to support the wrist join.		Y060609	
547	POLSINO ELASTICO NATURALE cm 8 – SIZE I POLSINO ELASTICO NATURALE cm 8 – SIZE II POLSINO ELASTICO NATURALE cm 8 – SIZE III POLSINO ELASTICO NATURALE cm 8 – SIZE IV POLSINO ELASTICO NATURALE cm 8 – SIZE V	Elastic protection to support the wrist join.		Y060609	
625	REGGIBRACCIO SOSTENITIVO – SIZE I REGGIBRACCIO SOSTENITIVO – SIZE II REGGIBRACCIO SOSTENITIVO – SIZE III REGGIBRACCIO SOSTENITIVO – SIZE IV	Arm support recommended after surgical operations or for the rehabilitations.		Y060699	
847	IMMOBIL. POLL-MANO-POLSO-AVAMBR. DX – SIZE I IMMOBIL. POLL-MANO-POLSO-AVAMBR. DX – SIZE II IMMOBIL. POLL-MANO-POLSO-AVAMBR. DX – SIZE III IMMOBIL. POLL-MANO-POLSO-AVAMBR. DX – SIZE IV	Orthopedic brace for the immobilization of the arm following fractures, traumas or surgical operations.		Y060609	
848	IMMOBIL. POLL-MANO-POLSO-AVAMBR. SX – SIZE I IMMOBIL. POLL-MANO-POLSO-AVAMBR. SX – SIZE II IMMOBIL. POLL-MANO-POLSO-AVAMBR. SX – SIZE III IMMOBIL. POLL-MANO-POLSO-AVAMBR. SX – SIZE IV	Orthopedic brace for the immobilization of the arm following fractures, traumas or surgical operations.		Y060609	
629	IMMOBIL. SPALLA/BRACCIO – ONE SIZE FITS FOR ALL	Orthopedic brace for the immobilization of the arm/shoulder, following fractures, traumas or surgical operations.		Y060699	
840	SUPPORTO POLSO-MANO – SIZE I SUPPORTO POLSO-MANO – SIZE II SUPPORTO POLSO-MANO – SIZE III SUPPORTO POLSO-MANO – SIZE IV	Orthopedic brace for the immobilization of the wrist join, following fractures, traumas or surgical operations.		Y060606	
841	SUPPORTO POLLICE – SIZE I SUPPORTO POLLICE – SIZE II	Orthopedic brace for the immobilization of the thumb, following inflammations and traumas.		Y060613	
845	IMMOBILIZZATORE DITA MANO – SIZE I IMMOBILIZZATORE DITA MANO – SIZE II IMMOBILIZZATORE DITA MANO – SIZE III IMMOBILIZZATORE DITA MANO – SIZE IV	Orthopedic brace for the immobilization of the fingers joins, following inflammations, traumas or after surgery.		Y060603	
842	SUPPORTO AVAMBRACCIO – ONE SIZE FITS FOR ALL	Orthopedic brace for the immobilization of the forearm, following inflammations and traumas.		Y060609	

860	COLLARE CERVICALE RIGIDO – SIZE I COLLARE CERVICALE RIGIDO – SIZE II COLLARE CERVICALE RIGIDO – SIZE III COLLARE CERVICALE RIGIDO – SIZE IV	Cervical collar recommended in cases of contractions, traumas and after surgery.		Y060312	
861	COLLARE CERVICALE SOFFICE cm 8 – SIZE I COLLARE CERVICALE SOFFICE cm 8 – SIZE II COLLARE CERVICALE SOFFICE cm 8 – SIZE III COLLARE CERVICALE SOFFICE cm 8 – SIZE IV	Cervical collar recommended in cases of contractions, traumas and after surgery.		Y060312	
862	COLLARE CERVICALE SOFFICE cm 10 – SIZE I COLLARE CERVICALE SOFFICE cm 10 – SIZE I COLLARE CERVICALE SOFFICE cm 10 – SIZE I COLLARE CERVICALE SOFFICE cm 10 – SIZE I	Cervical collar recommended in cases of contractions, traumas and after surgery.		Y060312	
656	MULTIBENDA SCUDOTEX cm 8 – LENGTH cm 260	Elastic cotton bandage, to bind up the legs.			
600	BENDA COTONE REKORDSAN cm 10 – SIZE I BENDA COTONE REKORDSAN cm 10 – SIZE II BENDA COTONE REKORDSAN cm 10 – SIZE III BENDA COTONE REKORDSAN cm 10 – SIZE IV BENDA COTONE REKORDSAN cm 10 – SIZE V BENDA COTONE REKORDSAN cm 10 – SIZE VI BENDA COTONE REKORDSAN cm 10 – SIZE VII BENDA COTONE REKORDSAN cm 10 – SIZE VIII	Elastic bandage to bind up the joints and the limbs.		M030401 0102	
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.		M030401 0102	
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 Viviani, 4 - 24040 CALVENZANO (BG)
Tel. 0363 86666 - Fax 0363 85281
Cod. Fisc. e Partita IVA 00683840169