



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
619	COPRISPALLE POLIESTENSIBILE LANA – SIZE I COPRISPALLE POLIESTENSIBILE LANA – SIZE II COPRISPALLE POLIESTENSIBILE LANA – SIZE III COPRISPALLE POLIESTENSIBILE LANA – SIZE IV COPRISPALLE POLIESTENSIBILE LANA – SIZE V COPRISPALLE POLIESTENSIBILE LANA – SIZE VI	Elasticized protection for shoulders in wool.	I, Rule 1 (Annex VIII of MDR2017/745)	Y060621	803261520PLUROPAS4Q
522	COSCIALE LANA POLIESTENSIBILE – SIZE I COSCIALE LANA POLIESTENSIBILE – SIZE II COSCIALE LANA POLIESTENSIBILE – SIZE III COSCIALE LANA POLIESTENSIBILE – SIZE IV COSCIALE LANA POLIESTENSIBILE – SIZE V	Elasticized protection for the thigh in wool.		M030405	
523	COSCIALE COTONE POLIESTENSIBILE – SIZE I COSCIALE COTONE POLIESTENSIBILE – SIZE II COSCIALE COTONE POLIESTENSIBILE – SIZE III COSCIALE COTONE POLIESTENSIBILE – SIZE IV COSCIALE COTONE POLIESTENSIBILE – SIZE V	Elasticized protection for the thigh in wool.		M030405	
521	GOMITIERA LANA POLIESTENSIBILE – SIZE I GOMITIERA LANA POLIESTENSIBILE – SIZE II GOMITIERA LANA POLIESTENSIBILE – SIZE III GOMITIERA LANA POLIESTENSIBILE – SIZE IV GOMITIERA LANA POLIESTENSIBILE – SIZE V	Elasticized protection for the elbow in wool.		Y060609	
524	GOMITIERA COTONE POLIESTENSIBILE – SIZE I GOMITIERA COTONE POLIESTENSIBILE – SIZE II GOMITIERA COTONE POLIESTENSIBILE – SIZE III GOMITIERA COTONE POLIESTENSIBILE – SIZE IV GOMITIERA COTONE POLIESTENSIBILE – SIZE V	Elasticized protection for the elbow in wool.		Y060609	
617	SOSPENSORIO COTONE UNIVERSAL – SIZE I SOSPENSORIO COTONE UNIVERSAL – SIZE II SOSPENSORIO COTONE UNIVERSAL – SIZE III SOSPENSORIO COTONE UNIVERSAL – SIZE IV SOSPENSORIO COTONE UNIVERSAL – SIZE V SOSPENSORIO COTONE UNIVERSAL – SIZE VI SOSPENSORIO COTONE UNIVERSAL – SIZE VII SOSPENSORIO COTONE UNIVERSAL – SIZE VIII	Support for man's genitals in cotton.		Y031299	
627	SOSPENSORIO COTONE PIEMONTE EXTRA – SIZE I SOSPENSORIO COTONE PIEMONTE EXTRA – SIZE II SOSPENSORIO COTONE PIEMONTE EXTRA – SIZE III SOSPENSORIO COTONE PIEMONTE EXTRA – SIZE IV SOSPENSORIO COTONE PIEMONTE EXTRA – SIZE V SOSPENSORIO COTONE PIEMONTE EXTRA – SIZE VI SOSPENSORIO COTONE PIEMONTE EXTRA – SIZE VII SOSPENSORIO COTONE PIEMONTE EXTRA – SIZE VIII SOSPENSORIO COTONE PIEMONTE EXTRA – SIZE IX SOSPENSORIO COTONE PIEMONTE EXTRA – SIZE X	Support for man's genitals in cotton.		Y031299	

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
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