



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
931	GUANCIALE PERSONAL FOAM	Anatomical pillows for a correct cervical support, body posture and spine alignment.	I, Rule 1 (Annex VIII of MDR2017/745)	Y060399	8032615200LUROPAS45
932	GUANCIALE COMFORT				
934	GUANCIALE ANTI-ACARO				
935	GUANCIALE RIPOSINO AERATO				
942	SOSTIENI COLLO			Y1299	
943	SALVA SCHIENA				
944	CUSCINO CUNEO				

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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