



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
676	MUTANDINA INCONTINENZA REGOLABILE – SIZE 1 MUTANDINA INCONTINENZA REGOLABILE – SIZE 2 MUTANDINA INCONTINENZA REGOLABILE – SIZE 3 MUTANDINA INCONTINENZA REGOLABILE – SIZE 4 MUTANDINA INCONTINENZA REGOLABILE – SIZE 5 MUTANDINA INCONTINENZA REGOLABILE – SIZE 6 MUTANDINA INCONTINENZA REGOLABILE – SIZE 7 MUTANDINA INCONTINENZA REGOLABILE – SIZE 8	Washable and waterproof unisex pants, for people who suffer from urinary incontinence, to be used with disposable diapers.	I, Rule 1 (Annex VIII of MDR2017/745)	T0499	803261520RLUROPAS5W

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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