



## DECLARATION OF CONFORMITY

**Manufacturer:**

Luropas del dottor Molinari &amp; 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
SP225	SCARPA POST OPERAT HALLUX VALGUS – SIZE 35/36 SCARPA POST OPERAT HALLUX VALGUS – SIZE 37/38 SCARPA POST OPERAT HALLUX VALGUS – SIZE 39/40 SCARPA POST OPERAT HALLUX VALGUS – SIZE 41/42 SCARPA POST OPERAT HALLUX VALGUS – SIZE 43/44 SCARPA POST OPERAT HALLUX VALGUS – SIZE 45/46	Hallux Valgus post-surgical shoe, recommended after hallux valgus and metatarsus	I, Rule 1 (Annex VIII of MDR2017/745)	Y063303	803261520VLUROPAS8A
SP230	SCARPA POST OPERAT HALLUX VALGUS OPEN – SIZE 35/36 SCARPA POST OPERAT HALLUX VALGUS OPEN – SIZE 37/38 SCARPA POST OPERAT HALLUX VALGUS OPEN – SIZE 39/40 SCARPA POST OPERAT HALLUX VALGUS OPEN – SIZE 41/42 SCARPA POST OPERAT HALLUX VALGUS OPEN – SIZE 43/44 SCARPA POST OPERAT HALLUX VALGUS OPEN – SIZE 45/46	surgeries and following foot injuries.		Y063303	
SP200	SCARPA COPRIGESSO PANNO – SIZE 1 SCARPA COPRIGESSO PANNO – SIZE 2 SCARPA COPRIGESSO PANNO – SIZE 3 SCARPA COPRIGESSO PANNO – SIZE 4 SCARPA COPRIGESSO PANNO – SIZE 5 SCARPA COPRIGESSO PANNO – SIZE 6 SCARPA COPRIGESSO PANNO – SIZE 7 SCARPA COPRIGESSO PANNO – SIZE 8 SCARPA COPRIGESSO PANNO – SIZE 9 SCARPA COPRIGESSO PANNO – SIZE 10 SCARPA COPRIGESSO PANNO – SIZE 11 SCARPA COPRIGESSO PANNO – SIZE 12	Plaster cast cover shoes.		Y090342	
SP210	SCARPA COPRIGESSO JEANS – SIZE 1 SCARPA COPRIGESSO JEANS – SIZE 2 SCARPA COPRIGESSO JEANS – SIZE 3 SCARPA COPRIGESSO JEANS – SIZE 4 SCARPA COPRIGESSO JEANS – SIZE 5 SCARPA COPRIGESSO JEANS – SIZE 6 SCARPA COPRIGESSO JEANS – SIZE 7 SCARPA COPRIGESSO JEANS – SIZE 8 SCARPA COPRIGESSO JEANS – SIZE 9 SCARPA COPRIGESSO JEANS – SIZE 10 SCARPA COPRIGESSO JEANS – SIZE 11 SCARPA COPRIGESSO JEANS – SIZE 12			Y090342	
RS25/D RS25/S	DIVARICATORE ALLUCE VALGO – RIGHT – ONE SIZE FITS FOR ALL DIVARICATORE ALLUCE VALGO – LEFT – ONE SIZE FITS FOR ALL	The Hallux Valgus Splint corrects the position of the hallux valgus. It constantly and rightly presses the big toe, favouring a correct positioning of it and avoiding the overlapping on the near toes.		Y061203	

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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