

## DECLARATION OF CONFORMITY

The undersigned Susanna Salvatelli as Legal Representative  
of the company **Optima Molliter S.R.L.**,  
with its legal and operative base in  
**Via Breda 19/21 - Z.Ind.le "A" - 62012 Civitanova Marche (MC) Italia**

declares under her own responsibility that

**Optima** systems included in the **Class I** of Medical Devices, according to the rule nr. 1 of the Annex VIII of the Regulation EU 2017/745 with basic UDI-DI code **805715830OPTIMALZ** and identified as follows

<b>REF NAME OF THE PRODUCT</b>	<b>DESCRIPTION OF THE PRODUCT</b>	<b>TO USE WITH</b>
OPTIMA EUROPA	Device for the management of interdigital diabetic ulcer/lesion, post-surgery of hallux valgus, hammer toes, Morton's neuroma, fractures/lesion of toes, nail excision, plantar wart excision.	OPTIMA PUZZLE KIT 3X3 OPTIMA PLTM

OPTIMA EUROPA

REG. N° 1717975

TYPE DM

CLASSIFICATION: FOOT ANKLE ORTHOSIS

GMDN: An externally applied orthopaedic appliance or apparatus used to encompass the ankle joint or the ankle and foot to support, align, prevent, or correct deformities/injuries or to improve function of the ankle and/or foot. This is a reusable device.

VALIDATION DATE: **28/06/2018**

are in compliance  
with the essential requirements of the Annex I of the Regulation EU 2017/745.

Civitanova Marche,  
04/08/2021

OPTIMA MOLLITER Srl  
(Legal Representative)

  
