

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

REF NAME OF THE PRODUCT	DESCRIPTION OF THE PRODUCT	TO USE WITH
OPTIMA POST OP	Device for the management of the diabetic plantar ulcer with vascular complications in the leg, neuroischemic ulcer (before and after revascularization. Management of the contralateral foot and management of the patient with risk of foot ulceration, closed metatarsal fracture, rehabilitation after toe amputation, preoperative stabilization, toe surgery, fractures of toes.	OPTIMA PUZZLE KIT 3X3 OPTIMA PLTM

OPTIMA POST OP

REG. N° 1717998

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)

