

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 **8057158300TPMALZ** and
identified as follows

REF NAME OF THE PRODUCT	DESCRIPTION OF THE PRODUCT	TO USE WITH
OPTIMA DIAB	Device for the management of the diabetic foot ulcer, plantar ulcer, post-amputation rehabilitation (up to transmetatarsal amputation) , rehabilitation after tarsus surgery, Charcot foot management during transition from acute to chronic phase, malleolar fracture, metatarsal fractures.	OPTIMA PUZZLE KIT 3X3 OPTIMA PLTM

OPTIMA DIAB

REG. N° 1717358

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: **27/06/2018**

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)