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 Regulamentation 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 CLHEEL	Device for the management of the plantar/dorsal heel diabetic ulcer, lesion of the tendon, decubitus of the heel, post- surgery rehabilitation of heel/Achilles tendon.	OPTIMA KITCLHEEL

OPTIMA CLHEEL

REG. N° 1718247
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: **29/06/2018**

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)

Optima Molliter srl
Via Breda 19/21 - Z.Ind.le "A" - 62012 Civitanova Marche (MC) Italy
VAT Number 01702040443
+39 0733 801060 - www.molliter.com