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
SBI 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 and with Basic UDI-DI code **805715830SBIM4** identified as follows

REF **NAME OF THE PRODUCT**	**DESCRIPTION OF THE PRODUCT**	**TO USE WITH**
SBI FRAME	Customizable device for the orthotic stabilisation , ankle fracture, severe ankle sprains, metatarsal fracture, post-operative use.	PLANTARE SBI 3X3 PLANTARE SBI PLTM

SBI FRAME

REG. N° 1717232
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)

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