

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 Regulation EU 2017/745 with Basic UDI-DI code **805715830SBIM4** and identified as
follows

NAME OF THE PRODUCT	DESCRIPTION OF THE PRODUCT	TO USE WITH
SBI W-HEEL	Customizable device for the management of the trauma/lesion of the tendon and of the heel.	PLANTARE SBI 3X3 PLANTARE SBI PLTM

SBI W-HEEL

REG. N° 1717258

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)


