

## 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 PLTM [REF Deutsch: OPTIMA TM]	Insole to protect the amputated foot and improve its position within the brace. It consists of three different parts connected by adhesive strips and velcro.	OPTIMA DIAB OPTIMA POST OP OPTIMA EUROPA OPTIMA FREE

OPTIMA PLTM  
[REF Deutsch: OPTIMA TM]

REG. N° 1718261

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)



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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 **805715830SBIM4** and  
identified as follows

REF NAME OF THE PRODUCT	DESCRIPTION OF THE PRODUCT	TO USE WITH
PLANTARE SBI PLTM [REF <i>Deutsch</i> : SBI TM INSOLE]	Insole to protect the amputated foot and improve its position within the brace. It consists of three different parts connected by adhesive strips and velcro.	SBI MOTUS SBI W-HEEL SBI FRAME

PLANTARE SBI PLTM

REG. N° 2059582

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: **27/01/2021**

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)

