

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 **805715830SBIM4** and identified
as follows

REF NAME OF THE PRODUCT	DESCRIPTION OF THE PRODUCT	TO USE WITH
PLANTARE SBI 3X3 [REF <i>Deutsch</i> : SBI INSOLE 3X3]	Plantar insole to redistribute plantar pressure in case of pressure ulcer on the forefoot, midfoot and heel and for personalized decompression of specific areas.	SBI FRAME SBI MOTUS SBI W-HEEL

PLANTARE SBI 3X3

[REF *Deutsch*: SBI INSOLE 3X3]

REG. N° 2059559

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)



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 PUZZLE KIT 3X3 [REF Deutsch: OPTIMA INSOLE 3X3]	Plantar insole to redistribute plantar pressure in case of pressure ulcer on the forefoot, midfoot and heel and for personalized decompression of specific areas.	OPTIMA DIAB OPTIMA POST OP OPTIMA EUROPA OPTIMA FREE

OPTIMA PUZZLE KIT 3X3
[REF Deutsch: OPTIMA INSOLE 3X3]
REG. N° 1717407

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)

DECLARATION OF CONFORMITY

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of the company **Optima Molliter S.R.L.**,
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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 KITCLHEEL [REF Deutsch: OPTIMA INSOLE 3X3]	Plantar insole to redistribute plantar pressure in case of pressure ulcer on the forefoot, midfoot and heel and for personalized decompression of specific areas.	OPTIMA CLHEEL

OPTIMA KITCLHEEL

[REF Deutsch: OPTIMA INSOLE 3X3]

REG. N° 1718252

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)