Declaration of Conformity

Version: 5.0

We

Calopad AG
Sonnmatthof 3
CH-6023 Rothenburg
Switzerland

Single Registration Number (SRN): CH-MF-000028271

Authorized Representative:

MED-RAS GmbH Regulatory Affairs Service
SRN DE-AR-000006211
Eichenallee 8H, 21521 Wohltorf,
Germany

Single Registration Number (SRN): DE-AR-000006211

declare under our sole responsibility that

the medical device(s):	**Calopad® (see article list on page 2)**
Class:	**IIa**
Rule:	**Rule 9**
Intended purpose:	**Calopad is intended to provide heating profiles at controlled temperatures through a powered heating pad that provides dry heat for body surfaces during noninvasive localized thermal therapy. With the help of different forms of therapy, different effects can be achieved in the area of muscle relaxation and pain relief. Calopad Thermal Foils are not intended to come in contact with breached or wounded skin.**
Basic UDI-DI:	**7640479932ACAL018L**

meet all the provisions of the directive 93/42/EEC as amended by directive 2007/47/EC which apply to it.

Conformity assessment procedure	**Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4; MDR 2017/745 Article 120**
Applied harmonised standards, national standards or other normative documents	**see "Regulatory and Normative Requirements, V 4.0"**
Notified Body	**CE 0068** **MTIC InterCert S.r.l.** **Via Moscova, 11 I-20017 Rho (MI)** **Italia**
EC Certificate number	0068/QCO-DM/167-2020

This declaration is valid for the products placed on the market between 22.04.2024 and 27.05.2025.

Rothenburg,

Michael Breiter, CEO

Article List

REF	Description
clp-set-800	Calopad® - Starter Set
clp-800	Calopad® - Controller
htf-8080	Calopad® - Heating foil 80mm x 80mm
htf-300150	Calopad® - Heating foil 300mm x 150mm
tape-8080	Calopad® - Tape 80mm x 80mm
tape-300150	Calopad® - Tape 300mm x 150mm