

Declaration of Conformity

Version: 3.0

calopad.

We

Calopad AG
Neuenkirchstrasse 19,
6203 Sempach Station
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

declare under our sole responsibility that

the medical device(s):

Class:

Rule:

Intended purpose:

Calopad® (see article list on page 2)

Ila

Rule 9

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:

764047993calopadBM

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 2.0"

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 26.05.2021 and 27.05.2024.

Sempach Station, 22.09.2022



Michael Breiter, CEO

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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