



EC-Konformitätserklärung / CE-Declaration of Conformity

Wir,
We,

medisana GmbH
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Tel. +49 (0) 2131 3668-0

erklären hiermit in alleiniger Verantwortung, dass das im folgenden aufgeführte Produkt, /
hereby state with sole responsibility that the product specified hereafter,

Medisana **FTN** Thermometer
Type: FR1DZ1
Art.-no.: 76120

gemäß Anhang IX, Regel 10 der im Folgenden aufgeführten Richtlinie der Klasse IIa zugeordnet ist:
has been assigned according to Annex IX, rule 10 to class IIa of the following directive:

Medizinprodukte-Richtlinie 93/42/EWG
medical device directive 93/42/EEC

Die Konformität mit den grundlegenden Anforderungen der Richtlinie MDD 93/42/EWG wurde
festgestellt gemäß Anhang VII in Verbindung mit Anhang VI unter Mitwirkung der folgenden
Benannten Stelle:

*The conformity with the essential requirements of the directive MDD 93/42/EEC, acc. to Annex VII in
connection with Annex VI has been assessed, at Annex VI with the participation of the Notified Body:*

DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt, GERMANY
mit der Kennung CE 0297.
with the registration no. CE 0297.

Diese Erklärung ist bis zum 26.05.2024 gültig.
This declaration is valid until 2024/5/26.

Neuss, Datum
date

29. April 2021

Mr. Thomas Hollefeld
Geschäftsführer / Managing director

Declaration of MDD certificate and CE-declaration extension

The medical products listed in the Annex are currently MDD CE-certificated with Medisana as the legal manufacturer under certificate no. 053432 MR6.

- Officially the certificate is valid until 26. May 2024.
- Based on the certificate, the corresponding CE-declaration for the products are also only valid until 26. May 2024.

As addressed in the regulation (EU) 2023/607 the current MDD CE-certification validity for products made available to the EU market before 26. May 2021, is extended, longest until 31. December 2028 (depending on the transition time to MDR).

As such, the corresponding CE declarations remain valid.

We cannot simply create a new CE declaration as there is no defined new end date.

We, Medisana GmbH, the legal manufacturer, hereby confirm:

that the named products were made available to the EU market before 26. May 2021

and

that the certificate and the belonging CE declaration for the listed MDD products are valid beyond the original named end date covered by the attached official confirmation of our NB DQS that the extension under regulation (EU)2023/607 is valid and the products still under control of DQS.

Name: Christoph Patten
Position: HoD QM & RA

Date: 23. Apr 2024

Company Stamp:

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Annex - List of belonging Products for MDD extension

Device name	MDD Device class	identification of the corresponding MDD/AIMDD device
Upper Arm BPM • MTP / MTP Pro / MTM • BU 510 / BU 512 / BU 514 / BU 516 / BU 520 / BU 530 / BU 535 (voice) / BU 540 / BU 542 / BU 546 / BU 565 / BU 570 connect / BU 580 connect/ BU 584 connect/ BU 582 / BU 586 • BU-90E / BU-92E / BU-94E / BU-97E • BU A50 / BU A52 / BU A55 / BU A57 / BU A65 / BU A66 / BU A70 • PR-B90	Class IIa	Devices for vital-parameter monitoring: Blood pressure Monitor MTx / BU(-)xxx
Wrist BPM • HGN / HGH • BW 315 / BW 320 / BW 335 • BW-84E / • BW A15 / BW A30 / BW A33 / BW A45	Class IIa	Devices for vital-parameter monitoring: Blood pressure Monitor HGx / BW(-)xxx
Contact Thermometer • FTC • TM 700 / TM 705 / TM 710 • TM-60E / TM-62E	Class IIa	Devices for vital-parameter monitoring: Electronic Thermometer FTx / TM(-)xxx
IR Thermometer • FTN / FTD / FTE • TM 750 (connect)/ TM 760 / TM 762 / TM 767 • TM-64E / TM-65E / TM-69E • TM A62/ TM A65 / TM A67 / TM A75	Class IIa	Devices for vital-parameter monitoring: Electronic Thermometer FTx / TM(-)xxx
Compressor Inhalor • IN 500 / IN 506 / IN 550 / IN 556	Class IIa	Device for inhalation: Inhalor IN(-)xxx
Ultrasonic Inhalor • IN 525 • IN A50	Class IIa	Device for inhalation: Inhalor IN(-)xxx
Pulse oximeter • PM 100 / PM150 • PM A10 / PM A19 / PM A20 / PM A21	Class IIa	Devices for vital-parameter monitoring: Pulse Oximeter PM(-)xxx
TENS device • TT 200 / TT 205 • TT-15E • TT A15	Class IIa	Devices for TENS treatment: TENS device TT(-)xxx
Infrared Lamp • IR 885	Class IIa	Devices for Infrared treatment: IR lamp IR(-)xxx