

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I,
Section 2 and 3 and Chapter III



Registration No.: HZ 2102042-1

Manufacturer: **OMRON HEALTHCARE Co., Ltd.**
53, Kunotsubo, Terado-cho,
Muko, KYOTO
617-0002 JAPAN

EUDAMED Single
Registration No.: JP-MF-000007213

Products: Products of Class IIa:

V030101 – THERMOMETERS
Z120302 – VITAL SIGNS MONITORING INSTRUMENTS
Y030306 – INHALATORS (ALSO NEBULIZERS AND HUMIDIFIERS not
classified in R)
Z120622 – TRANSCUTANEOUS ELECTRICAL NERVE STIMULATORS
N010201 – TENS SYSTEM ELECTRODES

Products of Class Im:

Z12099001 – BODY IMPEDANCE ANALYSERS

Authorised
representative(s): **Omron Healthcare Europe B.V.**
Scorpius 33, 2132 LR Hoofddorp,
The Netherlands

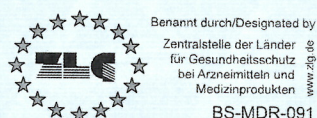
The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 150227798-200

Effective date: 2021-11-12

Expiry date: 2025-11-02

Issue date: 2021-11-12



Michiaki Aihara
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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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Certificate history		
Revision:	Description:	Issue date:
0	Initial	2021-07-07
1	Added product Y030306	2021-09-24
2	Added product Z120622, N010201, Z12099001	2021-11-12

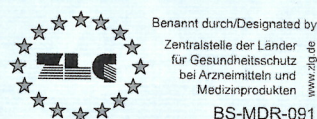
TÜVRheinland®

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