EU Certificate

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

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EU Certificate

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

TÜVRheinland®

Registration No.: HZ 2102042-1

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

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

Report No.: 150227798-200

Effective date: 2021-11-12

Expiry date: 2025-11-02

Issue date: 2021-11-12

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

M. Aihara

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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