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 R060101 – COLD NEBULISATION SYSTEMS N010201 – TENS SYSTEM ELECTRODES Z120628 – NEUROMUSCULAR STIMULATION EQUIPMENT Z121590 – VARIOUS PNEUMOLOGY AND RESPIRATORY PHYSIOPATHOLOGY INSTRUMENTS Products of class I, with measuring function: Z12099001 – BODY IMPEDANCE ANALYSERS The scope of certification is limited to the aspects relating to the conformity of the devices with the metrological requirements
Authorized representative(s):	Omron Healthcare Europe B.V. Wegalaan 73, 2132 JD 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.:	150292905-307
Effective date:	2024-04-05
Expiry date:	2026-07-06
Issue date:	2024-04-05

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

This certificate can be validated on https://www.certipedia.com

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2021-07-07
1	Added product Y030306	2021-09-24
2	Added product Z120622, N010201, Z12099001	2021-11-11
3	Replaced Y030306 with R060101	2022-11-18
4	Added product Z120628, Replaced Z120622 with Z120628	2023-01-27
5	Added product Z121590, Amendment regarding template text for Im and expiry date	2024-03-28
6	Authorized representative, changed address	2024-04-05

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