

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
Z120503 – ELECTROCARDIOGRAPHS
Z12050392 – ELECTROCARDIOGRAPHS - MEDICAL
DEVICE SOFTWARE
R030103 – AEROSOL THERAPY MASKS AND SYSTEMS

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.: 150301246-307

Effective date: 2024-12-17

Expiry date: 2026-07-06

Issue date: 2024-12-17



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.

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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

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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
7	Added product Z120503, Z12050392	2024-09-09
8	Added product R030103	2024-12-17

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