

Certificate

Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 2102042-1

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

Scope: Design and Development, Manufacture, Distribution and Service of
Electronic Sphygmomanometers,
Blood Pressure Monitors,
Clinical Electronic Thermometers,
Ear Thermometers,
Infrared Forehead Thermometers,
Inhalers,
Nebulizers,
Electroanalgesic Transcutaneous Stimulators,
Electroanalgesic Transcutaneous Stimulators Electrodes,
Electrocardiographs,
Cardiovascular Profiling Systems,
Body Composition Analyzers,
Body Fat Analyzers,
Wheeze Detectors,
Massage Machines,
Hearing Aids,
Body Composition Measuring Instruments,
Application Program Software,
Electronic Sphygmomanometers with Electrocardiograph function,
Application Program Software for Electrocardiogram,
Application Program Software for Hypertension Analysis and Reporting, and
Pulse Oximeters

Manufacture, Distribution, and Service of Automated External Defibrillators.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150329685-301

Effective date: 2026-08-28

Expiry date: 2029-08-27

Issue date: 2026-08-13

Replaces certificate SX 2102042-1 issued 2023-08-16

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



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617-0002 JAPAN

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o OMRON HEALTHCARE Co., Ltd. 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN	Design and Development, Manufacture and Distribution of Electronic Sphygmomanometers, Blood Pressure Monitors, Clinical Electronic Thermometers, Ear Thermometers, Infrared Forehead Thermometers, Inhalers, Nebulizers, Electroanalgesic Transcutaneous Stimulators, Electroanalgesic Transcutaneous Stimulators Electrodes, Electrocardiographs, Cardiovascular Profiling Systems, Body Composition Analyzers, Body Fat Analyzers, Wheeze Detectors, Massage Machines, Hearing Aids, Body Composition Measuring Instruments, Application Program Software, Electronic Sphygmomanometers with Electrocardiograph function, Application Program Software for Electrocardiogram, Application Program Software for Hypertension Analysis and Reporting, and Pulse Oximeters

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617-0002 JAPAN

The scope of certification also covers the following sites:

No.	Facility	Scope
/02	c/o OMRON HEALTHCARE Co., Ltd. Matsusaka Factory 1855-370, Kubo-cho, Matsusaka-shi, Mie, 515-8503 Japan	Manufacture, Distribution and Service of Electronic Sphygmomanometers, Blood Pressure Monitors, Clinical Electronic Thermometers, Ear Thermometers, Infrared Forehead Thermometers, Inhalers, Nebulizers, Electroanalgesic Transcutaneous Stimulators, Electroanalgesic Transcutaneous Stimulators Electrodes, Electrocardiographs, Cardiovascular Profiling Systems, Body Composition Analyzers, Body Fat Analyzers, Massage Machines, Hearing Aids, Body Composition Measuring Instruments, Automated External Defibrillators, Electronic Sphygmomanometers with Electrocardiograph function, and Pulse Oximeters

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Muko, KYOTO,
617-0002 JAPAN

The scope of certification also covers the following sites:

No.	Facility	Scope
/03	c/o OMRON HEALTHCARE Co., Ltd. Tokyo Branch Office 2-3-13, Konan, Minato-ku, Tokyo, 108-0075 Japan	Distribution of Electronic Sphygmomanometers, Blood Pressure Monitors, Clinical Electronic Thermometers, Ear Thermometers, Infrared Forehead Thermometers, Inhalers, Nebulizers, Electroanalgesic Transcutaneous Stimulators, Electroanalgesic Transcutaneous Stimulators Electrodes, Massage Machines, Electrocardiographs, Hearing Aids, Cardiovascular Profiling Systems, Body Composition Measuring Instruments, Body Fat Analyzers, Body Composition Analyzers, Automated External Defibrillators, and Pulse Oximeters
/04	c/o OMRON HEALTHCARE Co., Ltd. Hirakata Logistics Center 1-90-1, Nagaotani, Hirakata, Osaka, 573-0164 Japan	Manufacture of Electronic Sphygmomanometers, Blood Pressure Monitors, Clinical Electronic Thermometers, Inhalers, Nebulizers, Electroanalgesic Transcutaneous Stimulators, Electroanalgesic Transcutaneous Stimulators Electrodes, Massage Machines, Electrocardiographs, Hearing Aids, Body Fat Analyzers, Body Composition Analyzers, Automated External Defibrillators, and Pulse Oximeters

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