

Certificate

Quality Management System EN 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, Infrared Therapeutic Equipment, Massage Machines, Hearing Aids, Patient Monitors, Central Monitors, Body Motion Sensors, Body Composition Measuring Instruments, Application Program Software, Automated External Defibrillators, Electronic Sphygmomanometers with Electrocardiograph function, Application Program Software for Electrocardiogram, Application Program Software for Hypertension Analysis and Reporting, and Pulse Oximeter

In accordance with EN ISO 13485:2016 Medical devices
-Quality management systems –
Requirements for regulatory purposes (ISO 13485:2016)

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.	150277406-301
Effective date	2023-08-28
Expiry date	2026-08-27
Issue date	2023-08-16
Replaces certificate SX 2102042-1 issued 2022-03-04	



Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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53, Kunotsubo, Terado-cho,
Muko, KYOTO
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, 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, Infrared Therapeutic Equipment, Massage Machines, Hearing Aids, Patient Monitors, Central Monitors, Body Motion Sensors, 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 Oximeter
/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, Infrared Therapeutic Equipment, Massage Machines, Hearing Aids, Patient Monitors, Central Monitors, Body Motion Sensors, Body Composition Measuring Instruments, Automated External Defibrillators, Electronic Sphygmomanometers with Electrocardiograph function, and Pulse Oximeter

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

The scope of certification also covers the following sites:

- | | | |
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| /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, Infrared Therapeutic Equipment, Massage Machines, Electrocardiographs, Hearing Aids, Patient Monitors, Central Monitors, Cardiovascular Profiling Systems, Body Motion Sensors, Body Composition Measuring Instruments, Body Fat Analyzers, Body Composition Analyzers, Automated External Defibrillators, and Pulse Oximeter |
| /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, Ear Thermometers, Infrared Forehead Thermometers, Inhalers, Nebulizers, Electroanalgesic Transcutaneous Stimulators, Electroanalgesic Transcutaneous Stimulators Electrodes, Infrared Therapeutic Equipment, Massage Machines, Electrocardiographs, Hearing Aids, Patient Monitors, Body Motion Sensors, Body Composition Measuring Instruments, Body Fat Analyzers, Body Composition Analyzers, Automated External Defibrillators, and Pulse Oximeter |

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