

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2102042-1

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

Scope: Design and Development, Manufacture, Distribution and Servicing 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 and Application Program Software for Hypertension Analysis and Reporting

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.: 12031342 021
Effective date: 2021-08-28
Expiry date: 2023-08-27
Issue date: 2021-03-09



Ning Chang

Ning N. C. Chang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	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 and Application Program Software for Hypertension Analysis and Reporting

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53, Kunotsubo, Terado-cho,
Muko, KYOTO
617-0002 JAPAN

The scope of certification also covers the following:

/02 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 and Electronic
Sphygmomanometers with
Electrocardiograph function

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53, Kunotsubo, Terado-cho,
Muko, KYOTO
617-0002 JAPAN

The scope of certification also covers the following:

/03	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 and Automated External Defibrillators
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Muko, KYOTO
617-0002 JAPAN

The scope of certification also covers the following:

/04	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 and Automated External Defibrillators
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