

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 028488**

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

including the locations according to annex

Scope: Design and development, manufacture, sales, and servicing of electronic sphygmomanometers / blood pressure monitors, clinical electronic thermometers, ear thermometers, infrared forehead thermometers, inhalers, nebulizers, electroanalgesic transcutaneous stimulators, 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, pedometers, activity trackers, sleep time counters, weight scales, electric toothbrushes, wheeze detectors, electronic sphygmomanometers with electrocardiograph function, pulse oximeter
Design and development of program medical device, application program software for electrocardiogram, application program software for hypertension analysis and reporting
Manufacture (final acceptance activity), sales, and servicing of automated external defibrillators

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2023-08-22 until 2026-08-21.
First certification 2003

2023-08-18



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

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No.	Location	Scope
/01	c/o OMRON HEALTHCARE Co., Ltd. Katsuragawa Head Office 53, Kunotsubo, Terado-cho, Muko, KYOTO 617-0002 Japan	Design and development of electronic sphygmomanometers / blood pressure monitors, clinical electronic thermometers, ear thermometers, infrared forehead thermometers, inhalers, nebulizers, electroanalgesic transcutaneous stimulators, 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, program medical device, pedometers, activity trackers, sleep time counters, weight scales, electric toothbrushes, wheeze detectors, electronic sphygmomanometers with electrocardiograph function, application program software for electrocardiogram, application program software for hypertension analysis and reporting, pulse oximeter

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/02	<p>c/o OMRON HEALTHCARE Co., Ltd. Matsusaka Factory 1855-370, Kubo-cho, Matsusaka-shi, Mie, 515-8503 Japan</p>	<p>Manufacture, and servicing of electronic sphygmomanometers / blood pressure monitors, clinical electronic thermometers, ear thermometers, infrared forehead thermometers, inhalers, nebulizers, electroanalgesic transcutaneous stimulators, 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, pedometers, activity trackers, sleep time counters, weight scales, electric toothbrushes, electronic sphygmomanometers with electrocardiograph function, pulse oximeter Manufacture (final acceptance activity), and servicing of automated external defibrillators</p>
/03	<p>c/o OMRON HEALTHCARE Co., Ltd. Tokyo Branch Office 2-3-13, Konan, Minato-ku, Tokyo, 108-0075 Japan</p>	<p>Sales of electronic sphygmomanometers / blood pressure monitors, clinical electronic thermometers, ear thermometers, infrared forehead thermometers, inhalers, nebulizers, electroanalgesic transcutaneous stimulators, 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, pedometers, activity trackers, sleep time counters, weight scales, electric toothbrushes, wheeze detectors, electronic sphygmomanometers with electrocardiograph function, pulse oximeter</p>

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/04 c/o OMRON HEALTHCARE
Co., Ltd.
Hirakata Logistics Center
1-90-1, Nagatani,
Hirakata, Osaka,
573-0164 Japan

Manufacture (final acceptance activity) of
electronic sphygmomanometers / blood
pressure monitors, clinical electronic
thermometers, ear thermometers, infrared
forehead thermometers, inhalers, nebulizers,
electroanalgesic transcutaneous stimulators,
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, pedometers,
activity trackers, sleep time counters, weight
scales, electric toothbrushes, pulse oximeter
Manufacture of patient monitors

2023-08-18



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