

Number 908341

CERTIFICATE

OZAWA MEDICAL INSTRUMENTS Co., Ltd.

Kurashiki-shi, Okayama-ken, Japan

has implemented and maintains a

Quality Management System for Medical Devices which fulfills Nemko's provisions for Management System Certification and the requirements of the following standard

ISO 13485:2016

The certificate covers the following activities:

- Purchasing, Sales, and Incidental Services of Medical Imaging Information System
- Design, Development, Manufacture, Sales, and Incidental Services of Electromyograph and Electric Massagers for Home Use

Oslo, 2023-09-25

Helena Vogl

Nemko Scandinavia AS, Certification Department

 First time issued
 2014-12-02

 Expires
 2026-12-02





Certification document

Certification document no: 908341

Company name: OZAWA MEDICAL INSTRUMENTS Co., Ltd. 2355-10, Nakashima, Kurashiki-shi, Okayama-ken, 710-0803, Japan

The certification also covers the following departments and activities:

Head Office 2355-10, Nakashima, Kurashiki-shi, Okayama-ken, 710-0803, Japan	 Purchasing, Sales, and Incidental Services of Medical Imaging Information System Design, Development, Manufacture, Sales, and Incidental Services of Electromyograph and Electric Massagers for Home Use
Production Site 2355-25, Nakashima, Kurashiki-shi, Okayama-ken, 710-0803, Japan	Design, Production, and Other Related Processes

The certification according to ISO 13485:2016

was initially granted on 2014-12-02 in accordance with rules and regulations laid down by Nemko Scandinavia AS and Norwegian Accreditation (NA) as defined on the contracts last page.

The certification is granted under the condition that surveillance of the system is executed as a minimum once a year. The certificate expires 2026-12-02.

Oslo, 2023-09-25

Helena Vogl

Nemko Scandinavia AS, Certification Department

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