

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2100551-1

Organization: MANI, INC.
8-3 Kiyohara Industrial Park
Utsunomiya, Tochigi
321-3231 Japan

Scope: Design and Development, Manufacture, Sterilization (EOG), Distribution of
Medical Devices and Instruments in Surgical Fields.

Design and Development, Manufacture, Distribution of Medical Devices
and Instruments in Dental Fields.

Provision of Sterilization services for Medical Devices in Accordance with
EN ISO 11135:2014.

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.: 150265342-301

Effective date: 2022-11-24

Expiry date: 2023-11-26

Issue date: 2022-11-24



Michiaki Aihara

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

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Utsunomiya, Tochigi
321-3231 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o MANI, INC. Kiyohara Factory 8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 321-3231 Japan	Design and Development, Manufacture, Sterilization (EOG), Distribution of Surgical Needles, Surgical Sutures, Surgical Suturing Devices, Medical Knives, Medical Saws, Bone Fixation Devices and Ophthalmic Cannulae. Design and Development, Distribution of Dental Endodontic Instruments and Dental Rotary Instruments. Provision of Sterilization services for Medical Devices in Accordance with EN ISO 11135:2014.
/02	c/o MANI, INC. Takanezawa Factory 743 Nakaakutsu, Takanezawa, Tochigi, 329-1234 Japan	Manufacture of Dental Endodontic Instruments and Dental Rotary Instruments.

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321-3231 Japan

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /03 | c/o MANI HANOI CO., LTD. Pho Yen Factory
Vang Residential Group,
Tan Huong Ward, Pho Yen City,
Thai Nguyen Province,
Vietnam | Manufacture, Sterilization (EOG) of Surgical Sutures, Surgical Suturing Devices, Medical Knives, Medical Saws, Bone Fixation Devices and Ophthalmic Cannulae. |
| /04 | c/o MANI HANOI CO., LTD. Pho Yen 2 Factory
Plot CN5, Diem Thuy Industrial Zone - Area A, Hong Tien Ward, Pho Yen City,
Thai Nguyen Province,
Vietnam | Manufacture of Dental Endodontic Instruments and Dental Rotary Instruments.

Manufacture, Sterilization (EOG) of Surgical Needles and Surgical Sutures. |

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