

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2100551-1

Certificate Holder: 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.: 150300087-301

Effective date: 2024-12-19

Expiry date: 2026-11-26

Issue date: 2024-12-19

Replaces certificate SX 2100551-1 issued 2024-12-11

This certificate can be validated on <https://www.certipedia.com>



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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o MANI, INC. Kiyohara Factory 8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 321-3231, Japan	Design and Development, Manufacture, Distribution of Surgical Needles. Design and Development, Manufacture, Sterilization (EOG), Distribution of Surgical Sutures, Surgical Suturing Devices, Medical Knives, Bone Fixation Devices, Ophthalmic Cannulae and Ophthalmic Surgery Instruments. Design and Development, Manufacture, Distribution of Sterile Dental Endodontic Instruments. Design and Development, Distribution of Non-Sterile 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 Non-Sterile Dental Endodontic Instruments and Dental Rotary Instruments. Manufacture of Non-Sterile Subassemblies for Sterile Dental Endodontic Instruments.
/03	c/o MANI HANOI CO., LTD. Pho Yen Factory Vang Residential Group, Tan Huong Ward, Pho Yen City, Thai Nguyen Province, Vietnam	Manufacture of Bone Fixation Devices, Ophthalmic Cannulae, Dental Endodontic Instruments and Dental Rotary Instruments. Manufacture, Sterilization (EOG) of Surgical Sutures, Surgical Suturing Devices, Medical Knives.
/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 Surgical Needles. Manufacture, Sterilization (EOG) of Surgical Sutures.

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