

# Certificate

Certificate No.: MD 2100551-1-4

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

REPs Facility ID: F003084

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,  
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance  
Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,  
RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282,  
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68,  
PMD Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –  
Subparts A to D

Scope: Design and Development, Manufacture, Distribution of Surgical  
Needles, Surgical Sutures, Surgical Suturing Devices, Medical  
Knives, Bone Fixation Devices, Ophthalmic Cannulae, Ophthalmic  
Surgery Instruments, Dental Endodontic Instruments and Dental  
Rotary Instruments.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 150300087-302

Issue Date: 2024-12-19

Effective Date: 2024-12-19

Expiry Date: 2026-11-21



Certification officer: Michiaki Aihara  
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>  
or calling 1-888-743-4652.

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The scope of certification also covers the following sites:

No.	Location	Scope
/01	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.  REPs Facility ID: F003084
/02	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.  REPs Facility ID: F003154



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The scope of certification also covers the following sites:

- |     |   |  |
|-----|---|--|
| /03 | MANI HANOI CO., LTD. Pho Yen Factory<br>Vang Residential Group,<br>Tan Huong Ward, Pho Yen City,<br>Thai Nguyen Province,<br>Vietnam                            | Manufacture of Bone Fixation Devices,<br>Ophthalmic Cannulae, Dental Endodontic<br>Instruments and Dental Rotary Instruments.<br><br>Manufacture, Sterilization (EOG) of Surgical<br>Sutures, Surgical Suturing Devices, Medical<br>Knives.<br><br>REPs Facility ID: F003155 |
| /04 | MANI HANOI CO., LTD. Pho Yen 2<br>Factory<br>Plot CN5, Diem Thuy Industrial Zone -<br>Area A, Hong Tien Ward, Pho Yen City,<br>Thai Nguyen Province,<br>Vietnam | Manufacture of Surgical Needles.<br><br>Manufacture, Sterilization (EOG) of Surgical<br>Sutures.<br><br>REPs Facility ID: F003156  |

**TÜV Rheinland**



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