Certificate

Certificate No.:	MD 2100551-1-2
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, Medical Saws, 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.:	150278228-302
Issue Date:	2023-11-22
Effective Date:	2023-11-22
Expiry Date:	2026-11-21

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Atsushi Kato
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000009600?locale=en or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 2100551-1-2

Manufacturer: **MANI, INC.**

8-3 Kiyohara Industrial Park,
Utsunomiya, Tochigi,
321-3231, Japan

The scope of certification includes the following additional 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, Medical Saws, Bone Fixation Devices, Ophthalmic Cannulae and Ophthalmic Surgery Instruments. Design and Development, Distribution of 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 Dental Endodontic Instruments and Dental Rotary Instruments. REPs Facility ID: F003154

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Certificate

Certificate No.: MD 2100551-1-2

Manufacturer: **MANI, INC.**

8-3 Kiyohara Industrial Park,
Utsunomiya, Tochigi,
321-3231, Japan

The scope of certification includes the following additional sites:

/03	MANI HANOI CO., LTD. Pho Yen Factory Vang Residential Group, Tan Huong Ward, Pho Yen City, Thai Nguyen Province, Vietnam	Manufacture of Medical Saws, Bone Fixation Devices, Ophthalmic Cannulae, Dental Endodontic Instruments and Dental Rotary Instruments. Manufacture, Sterilization (EOG) of Surgical Sutures, Surgical Suturing Devices, Medical Knives. REPs Facility ID: F003155
/04	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. REPs Facility ID: F003156

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Expiry Date: 2026-11-21

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Atsushi Kato
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