



# 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, Distribution of Medical Devices  
and Instruments in Surgical and 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.: 150227667-410  
Effective date: 2020-11-27  
Expiry date: 2021-11-26  
Issue date: 2020-11-26



*M. Aihara*

M. Sc. M. Aihara  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany





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The scope of certification also covers the following:

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

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- |     |   |  |
|-----|---|--|
| /03 | MANI HANOI CO., LTD. Pho Yen Factory<br>Tan Huong Commune, Pho Yen Town,<br>Thai Nguyen Province, Vietnam 257170  | Manufacture of Surgical Sutures, Surgical<br>Suturing Devices, Medical Knives, Medical<br>Saws, Bone Fixation Devices, Ophthalmic<br>Cannulae, Dental Endodontic Instruments,<br>Dental Rotary Instruments |
| /04 | MANI HANOI CO., LTD. Pho Yen 2<br>Factory<br>Plot CN5, Diem Thuy Industrial Zone,<br>Hong Tien Commune, Pho Yen Town,<br>Thai Nguyen Province, Vietnam 256800 | Manufacture of Surgical Needles and<br>Surgical Sutures  |
| /05 | MANI YANGON LTD.<br>Plot No. 630, Hle Ngote Chaung Kwin,<br>Yangon-Pyay Road, Hmawbi Township,<br>Yangon, Myanmar   | Manufacture of Surgical Needles and Dental<br>Endodontic Instruments   |

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