



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**MANI, INC.**  
8-3 Kiyohara Industrial Park,  
Utsunomiya,  
Tochigi, 321-3231,  
Japan

has established and applies a quality management system for medical devices  
for the following scope:

**see attachments for scope of certification**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-03-12  
Certificate Registration No.: SX 60137134 0001  
An audit was performed. Report No.: 12022703 012  
This Certificate is valid until: 2020-11-26

Certification Body



Date 2019-03-12



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety







Doc. 1/5, Rev.0

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60137134 0001  
**Report No.:** 12022703 012

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

**Scope:**

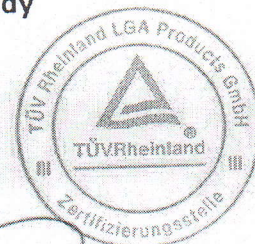
Design and Development, Manufacture, Distribution of  
Medical Devices and Instruments in Surgical and  
Dental Fields



**Certification Body**



Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02



**Date:** 2019-03-12

**Masahiro Asami**





Doc. 2/5, Rev.0

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.: SX 60137134 0001**

**Report No.: 12022703 012**

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

**Scope: Products and Site included:**

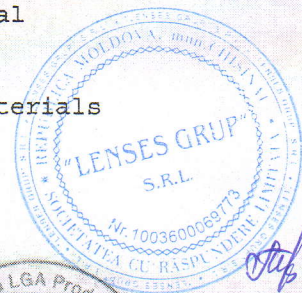
Kiyohara Factory  
8-3 Kiyohara Industrial Park, Utsunomiya,  
Tochigi, 321-3231, Japan

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, Dental  
Pins and Posts

Distribution of Dental Root Canal Filling Materials

**Certification Body**



**Date: 2019-03-12**

**Masahiro Asami**





Doc. 3/5, Rev.0

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60137134 0001  
**Report No.:** 12022703 012

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

**Scope:** Products and Site included:

Takanezawa Factory  
743 Nakaakutsu, Takanezawa, Tochigi, 329-1234, Japan

Manufacture of Dental Endodontic Instruments, Dental Rotary  
Instruments and Dental Pins and Posts

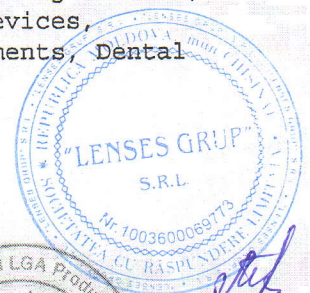
MANI HANOI CO., LTD. PHO YEN FACTORY  
Tan Huong Commune, Pho Yen Town, Thai Nguyen Province,  
Vietnam

Manufacture of Surgical Sutures, Surgical Suturing Devices,  
Medical Knives, Medical Saws, Bone Fixation Devices,  
Ophthalmic Cannulae, Dental Endodontic Instruments, Dental  
Rotary Instruments and Dental Pins and Posts

**Certification Body**



Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02



**Date:** 2019-03-12

**Masahiro Asami**





**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 4/5, Rev.0

**Attachment to  
Certificate**

**Registration No.:** SX 60137134-0001  
**Report No.:** 12022703 012

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

**Scope:**

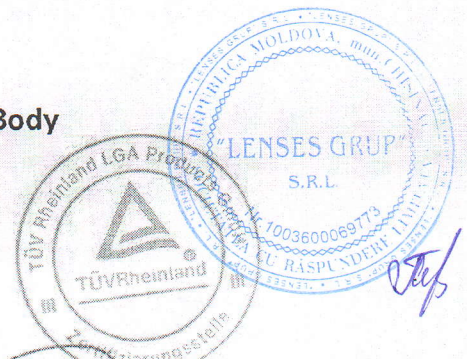
Products and Site included:

MANI HANOI CO., LTD. PHO YEN 2 FACTORY  
Plot CNS, Diem Thuy Industrial Zone, Hong Tien Commune,  
Pho Yen Town, Thai Nguyen Province, Vietnam

Manufacture of Surgical Needles and Surgical Sutures



**Certification Body**



**Date:** 2019-03-12

  
**Masahiro Asami**





Doc. 5/5, Rev.0

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

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Certificate**

**Registration No.:** SX 60137134 0001  
**Report No.:** 12022703 012

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

**Scope:** Products and Site included:

MANI YANGON LTD.  
Plot No. 630, Hle Ngote Chaung Kwin, Yangon-Pyay Road,  
Hmawbi Township, Yangon, Myanmar

Manufacture of Surgical Needles and Dental Endodontic  
Instruments

**Certification Body**



**Date:** 2019-03-12

  
**Masahiro Asami**