



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

Masahiro Asami

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:

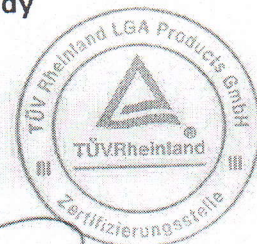
Design and Development, Manufacture, Distribution of
Medical Devices and Instruments in Surgical and
Dental Fields



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:

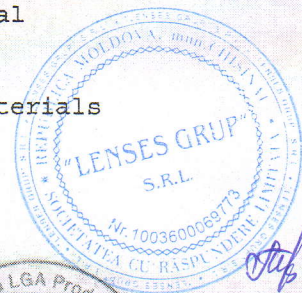
Kiyohara Factory
8-3 Kiyohara Industrial Park, Utsunomiya,
Tochigi, 321-3231, Japan

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

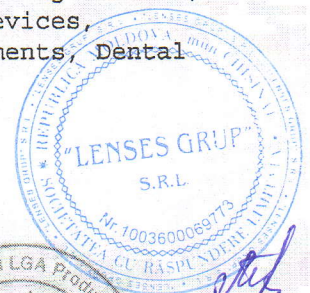
MANI HANOI CO., LTD. PHO YEN FACTORY
Tan Huong Commune, Pho Yen Town, Thai Nguyen Province,
Vietnam

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:

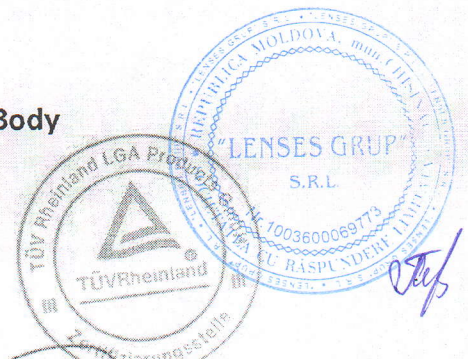
Products and Site included:

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

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:

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