



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60142912 0001

Report No.: 12022703 018

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

Products: Medical Devices and Instruments in Surgical and
Dental Fields
(see attachment for sites and products included)

Replaces Approval, Registration No.: HD 60097627 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-09-20

Date: 2019-09-20



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/3, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60142912 0001
Report No.: 12022703 018

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

Products included:

- Surgical Needles
- Surgical Sutures
- Surgical Suturing Devices
- Dental Rotary Instruments
- Dental Endodontic Instruments
- Dental Pins and Posts
- Medical Knives
- Bone Fixation Devices
- Medical Saws
- Ophthalmic Cannulae
- Dental Root Canal Filling Materials

Notified Body

M. Aihara

M.Sc. M. Aihara



Date: 2019-09-20



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60142912 0001
Report No.: 12022703 018

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

Design and Development, Manufacturing sites included:

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

Manufacturing sites included:

MANI, INC., Takanezawa Factory
743 Nakaakutsu, Takanezawa, Tochigi, 329-1234, Japan

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

MANI HANOI CO., LTD. PHO YEN 2 FACTORY
Plot CN5, Diem Thuy Industrial Zone, Hong Tien Commune,
Pho Yen Town, Thai Nguyen Province, Vietnam

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

Notified Body

Date: 2019-09-20

M. Aihara
M.Sc. M. Aihara





TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/3, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60142912 0001
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Manufacturer: MANI, INC.
8-3 Kiyohara Industrial Park,
Utsunomiya,
Tochigi, 321-3231,
- Japan

EOG Sterilization sites and products included:

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

- Surgical Sutures
- Surgical Suturing Devices
- Medical Knives
- Bone Fixation Devices
- Medical Saws
- Ophthalmic Cannulae

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

- Surgical Sutures
- Surgical Suturing Devices
- Medical Knives

MANI HANOI CO., LTD. PHO YEN 2 FACTORY
Plot CN5, Diem Thuy Industrial Zone, Hong Tien Commune,
Pho Yen Town, Thai Nguyen Province, Vietnam

- Surgical Sutures

Notified Body

Date: 2019-09-20

M. Aihara
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