

## **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

Prinizierungssell 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.

TÜVRheinland



Doc. 1/3, Rev. 0

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

Attachment to Certificate

Registration No.: Report No.:

HD 60142912 0001 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** 

Walerun955

TÜVRheinland

M.Sc. M. Aihara

Date: 2019-09-20



TÜVRheinland

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

Doc. 2/3, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

HD 60142912 0001 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** 

M.Sc. M. Aihara

Date: 2019-09-20



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg Doc. 3/3, Rev. 0

JUGA Progr

TÜVRheinland

Attachment to Certificate

Registration No.: Report No.:

HD 60142912 0001 12022703 018

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** 

M.Sc. M. Aihara

Date: 2019-09-20