

**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**

**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**

**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.Sc. M. Aihara**



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

**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**

**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

**Date: 2019-09-20**

**Notified Body**

  
**M.Sc. M. Aihara**

