

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

Registration No.: HD 60097627 0001

Report No.: 12022703 001

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)

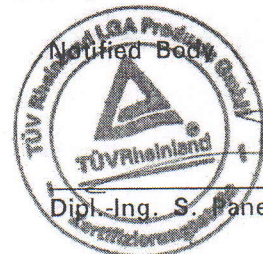
Replaces Approval, Registration No.: HD 60041244 0001

Expiry Date: 2019-12-10

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: 2015-10-05

Date: 2015-10-05



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**

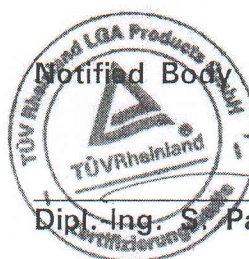
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Products included:

- 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

Date: 2015-10-05



Dipl.-Ing. S. Pane



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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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

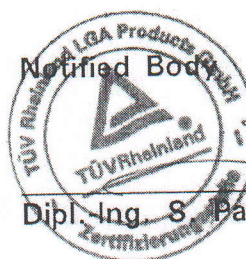
MANI, INC., Takanezawa Factory
743, Nakaakutsu, Takanezawa, Tochigi, 329-1234, Japan

EOG sterilization site:

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

Date: 2015-10-05



Dipl.-Ing. S. Pane

