TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Notified Body

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.

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

TÜVRheinland®

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

Date: 2019-09-20

maihara

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

TÜVRheinland®

Doc. 2/3, Rev. 0

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

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2019-09-20

maihara

M.Sc. M. Aihara

TÜVRheinland®

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

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2019-09-20

m.aihara

M.Sc. M. Aihara

EC Certificate

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

TÜVRheinland®

Registration No.: HD 60135991 0001

Report No.: 21208078 021

Manufacturer:
Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Deutschland

Products:
Non-active medical devices

(see attachment for products included)

Replaces Approval, Registration-No.: HD 60091372 0001

Expiry Date: 2024-01-19

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: 2019-01-20

Date: 2019-01-17

Notified Body

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

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.

LIETUVOS RESPUBLIKA
Mažoji bendrija
„Protingi medicinos sprendimai"
VILNIUS

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60135991 0001
Report No.: 21208078 021

Manufacturer:
Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Deutschland

Products included:

- Rotary and oscillating instruments for dentistry
- Rotary instruments and saw blades for orthopedics, dermatology, surgery and ophthalmology
- Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth
- Composite systems for root post cementation and core build-up
- Instruments for podiatry
- Agents for the cleaning and disinfection of medical devices
- Pins and screws for use in orthopedics
- Rotary endodentic instruments
- Filling material for root canals and paper points for drying the root canal
- Dental hand pieces and contra-angles

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dr. K. Kluge

Date: 2019-01-17

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60135991 0001
Report No.: 21208078 021

Manufacturer:
Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Deutschland

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- Manual instruments and tools for use in dentistry

Notified Body

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

Date: 2019-01-17

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

REGER Medizintechnik GmbH
Gewerbestraße 10
78667 Villingendorf
Germany

for the scope

Instruments and accessories for surgery and electro surgery
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2018-07-30
Valid until	2023-07-29
Registration no.	D1228500011
Report no.	P18-00423-117158
Stuttgart	2018-07-27

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1228500011 Date 2018-07-27 Page 1 of 1

Product category	Product	Class	Product code
Instruments and accessories for surgery and electro surgery	HF-Handles (controllable)	IIb	11-499
	HF-Handles (non-controllable)	IIa	11-499
	Bipolar forceps	IIb	11-502
	HF-Electrodes, monopolar and bipolar	IIb	15-579
	Micropump (CapnoPen)	IIa	16-722
	Bipolar Scissors/ Clamp-Scissors	IIb	16-860
	HF-Neutral Electrodes	IIb	11-500

Head of Certification Body

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de