TÜVRheinland®

EC Certificate

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

Registration No.: HD 60142912 0001

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

Products: Medical Devices and Instruments in Surgical and Dental Fields.

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

Digitally signed by Benderschi Tamara
Date: 2025.09.11 14:42:41 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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.

Report No.: 150239116-210

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25

TÜV Rheinland LGA Products GmbH Zertifizierung TÜVRheinland

Michiaki Aihara
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

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

Registration No.: HD 60142912 0001

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

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	MANI, INC. Kiyohara Factory 8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 321-3231, Japan	EOG Sterilization: - Surgical Sutures - Surgical Suturing Devices -Medical Knives - Bone Fixation Devices - Medical Saws - Ophthalmic Cannulae
/02	MANI, INC. Takanezawa Factory 743 Nakaakutsu, Takanezawa, Tochigi, 329-1234, Japan	
/03	MANI HANOI CO., LTD. PHO YEN FACTORY Tan Huong Commune, Pho Yen Town, Thai Nguyen Province, Vietnam 257170	EOG Sterilization: - Surgical Sutures - Surgical Suturing Devices - Medical Knives

Report No.: 150239116-210

Effective date: 2021-05-25

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

M.aihara

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EC Certificate

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

Registration No.: HD 60142912 0001

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

The scope of certification includes the following manufacturing sites:

/04	MANI HANOI CO., LTD. PHO YEN 2 FACTORY Plot CN5, Diem Thuy Industrial Zone, Hong Tien Commune, Pho Yen Town, Thai Nguyen Province, Vietnam 256800	EOG Sterilization: - Surgical Sutures

Report No.: 150239116-210

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25

TÜV Rheinland LGA Products GmbH Zertifizierungs

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

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Business Stream Products
Certification Department

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LGA
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TÜV Rheinland LGA Products GmbH • 51105 Köln

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321-3231 Japan

Contact

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Date December 22, 2023

Notified Body Confirmation Letter
Reference. : MANI_ CL607_2023-12-22

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MANI, INC.
8-3 KIYOHARA INDUSTRIAL PARK, UTSUNOMIYA
TOCHIGI, 321-3231 JAPAN
SRN Number: JP-MF-000017860

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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LGA Products GmbH

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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Ning Chang

Ning N. C. Chang
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MANI REAMERS, MANI MEDIUM REAMERS	Ir	N/A	HD 60142912 0001 NB# 0197
MANI K-FILES, MANI MEDIUM K-FILES, MANI FLEXILE FILES, MANI MEDIUM FLEXILE FILES, MANI SEC O-FILES, K, MANI GLIDE FINDERS	Ir	N/A	HD 60142912 0001 NB# 0197
MANI H-FILES, MANI MEDIUM H-FILES, MANI SEC O-FILES, H	Ir	N/A	HD 60142912 0001 NB# 0197
MANI FLARE FILES, MANI MEDIUM FLARE FILES	Ir	N/A	HD 60142912 0001 NB# 0197
MANI RT FILES	Ir	N/A	HD 60142912 0001 NB# 0197
MANI D FINDERS	Ir	N/A	HD 60142912 0001 NB# 0197
MANI SHORT BARBED BROACHES	Ir	N/A	HD 60142912 0001 NB# 0197
MANI SPREADERS, MANI FLARE SPREADERS	Ir	N/A	HD 60142912 0001 NB# 0197
MANI SUTURES SILK, MANI SUTURES VIRGIN SILK, MANI SUTURES SILK / VIRGIN SILK, MANI SUTURES	IIb	N/A	HD 60142912 0001 NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MANI SUTURES POLYPROPYLENE MANI SUTURES	IIb	N/A	HD 60142912 0001 NB# 0197
MANI SUTURES NYLON, MANI SUTURES	IIb	N/A	HD 60142912 0001 NB# 0197
MANI SUTURES POLYESTER, MANI SUTURES	IIb	N/A	HD 60142912 0001 NB# 0197
Manipler, ManiplerS-2, Manipler S-2 35W, Manipler S-2 35W Disposable Skin Stapler, ManiplerS-2 Skin Stapler	IIa	N/A	HD 60142912 0001 NB# 0197
ManiplerAZ, ManiplerDSX, MANI Skin Stapler, Manipler AZ 35W, Manipler DSX 35W, Manipler AZ 35W Disposable Skin Stapler, Manipler DSX 35W Disposable Skin Stapler, Manipler AZ Skin Stapler	IIa	N/A	HD 60142912 0001 NB# 0197
MANI OPHTHALMIC KNIFE, MANI OPHTHALMIC KINFE STRAIGHT, MANI OPHTHALMIC KNIFE CRESCENT, MANI OPHTHALMIC KNIFE MVR, MANI OPHTHALMIC KNIFE MPK, MANI OPHTHALMIC KINFE SLIT, MANI OPHTHALMIC KNIFE R SLIT(IMPLANT), MANI OPHTHALMIC KNIFE GOLF/SCLERAL, MANI OPHTHALMIC KNIFE GUARD, MANI OPHTHALMIC KNIFE DOUBLE STEP ANGLED 1.0MM, MANI OPHTHALMIC KNIFE UNIVERSAL	IIa	N/A	HD 60142912 0001 NB# 0197
MANI TROCAR KIT MANI TROCAR MANI INFUSION CANNULA	IIa	N/A	HD 60142912 0001 NB# 0197
MANI TROCAR KIT MANI TROCAR	IIa	N/A	HD 60142912 0001 NB# 0197
MANI TROCAR KIT MANI INFUSION CANNULA	IIa	N/A	HD 60142912 0001 NB# 0197
MANI ENGINE REAMERS	IIa	N/A	HD 60142912 0001 NB# 0197
MANI SUPER FILES	IIa	N/A	HD 60142912 0001 NB# 0197
MANI U-FILES	IIa	N/A	HD 60142912 0001 NB# 0197
MANI JIZAI, MANI NiTi FILES, JIZAI GLIDER	IIa	N/A	HD 60142912 0001 NB# 0197
MANI PEESO REAMERS	IIa	N/A	HD 60142912 0001 NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MANI GATES DRILLS	IIa	N/A	HD 60142912 0001 NB# 0197
MANI CARBIDE BURS	IIa	N/A	HD 60142912 0001 NB# 0197
MANI DIA-BURS	IIa	N/A	HD 60142912 0001 NB# 0197
MANI STAINLESS BURS	IIa	N/A	HD 60142912 0001 NB# 0197
MANI STAINLESS BURS HARD	IIa	N/A	HD 60142912 0001 NB# 0197
MANI PASTE CARRIERS, Paste Fillers	IIa	N/A	HD 60142912 0001 NB# 0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-12-13	MANI_ CL607_2023-12-13	Initial issue
2023-12-22	MANI_ CL607_2023-12-22	Delete non-relevant text