Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

MANI, INC.
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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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.

Digitally signed by Benderschi Tamara
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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