Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

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Japan

Contact

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Date May 22, 2024

Notified Body Confirmation Letter
Reference. : Nakanishi_MDR Application 2024-05-13; order # 150293209

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:

Nakanishi Inc.
700 Shimohinata, Kanuma,
Tochigi, 322-8666
Japan
SRN Number: JP-MF-000011271

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. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

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:

- 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

On behalf of the Notified Body

Michiaki Aihara
Certification body

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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
X-DSG20L (X-DSG20 + 3 models)	IIa	N/A	Certificate # HD 60148508 0001 NB # 0197
Perio Mate Powder	IIa	N/A	Same as above
Perio-Mate (PER-PTL-HP + 6 models)	IIa	N/A	Same as above
Surgic Pro (Surgic Pro+ OPT EU Q + 8 models)	IIa	N/A	Same as above
Surgic Pro2 (Surgic Pro2 OPT EU + 1 model)	IIa	N/A	Same as above
Perio Mate Nozzle Tip	IIa	N/A	Same as above
Ti-Max (Z800L + 23 models)	IIa	N/A	Same as above
H311L	IIa	N/A	Same as above
H511L	IIa	N/A	Same as above
Pana-Max2 (Pana-Max2 M4 + 6 models)	IIa	N/A	Same as above
Pana-Max PLUS2 (PAP2-SU QD + 5 models)	IIa	N/A	Same as above
Pana-Max PLUS (PAP-SU M4 + 5 models)	IIa	N/A	Same as above
PanaAir FX (PAF-SU M4 + 4 models)	IIa	N/A	Same as above
FX Plus (FXP-SU QD +5 models)	IIa	N/A	Same as above
S-Max (S-Max pico + 4 models)	IIa	N/A	Same as above
DynaLED (M600LG M4 + 5 models)	IIa	N/A	Same as above
S-Max (M800 + 13 models)	IIa	N/A	Same as above
Ti-Max (Z micro + 2 models)	IIa	N/A	Same as above
S-Max (M micro + 2 models)	IIa	N/A	Same as above
Ti-Max (X450QD + 5 models)	IIa	N/A	Same as above
Ti-Max (Z15L + 17 models)	IIa	N/A	Same as above
S-Max (M15 + 5 models)	IIa	N/A	Same as above
E205IL	IIa	N/A	Same as above
E200IL	IIa	N/A	Same as above
FX (FX25m + 5 models)	IIa	N/A	Same as above
A200E	IIa	Air Motor AE Set/Model:AE SET	Same as above
FFB-EC	IIa	N/A	Same as above
FFB-ECM	IIa	N/A	Same as above
FPB-EC	IIa	N/A	Same as above
FPB-ECM	IIa	N/A	Same as above
NAC-EC	IIa	N/A	Same as above
NAC-ER16	IIa	N/A	Same as above
NBB-EC	IIa	N/A	Same as above
NBBW-EC	IIa	N/A	Same as above
BB-EC	IIa	N/A	Same as above
Ti-Max (X65L + 2 models)	IIa	N/A	Same as above
S-Max	IIa	N/A	Same as above
E400I	IIa	N/A	Same as above
EX-6B	IIa	N/A	Same as above
EX-5B	IIa	N/A	Same as above
FX (FX65m + 1 model)	IIa	N/A	Same as above

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
A400E	IIa	Air Motor AE Set/Model:AE SET	Same as above
Ti-Max (X35L + 1 model)	IIa	N/A	Same as above
Ti-ENDO	IIa	N/A	Same as above
FX(FX75 + 1 model)	IIa	N/A	Same as above
MPA-ER16	IIa	N/A	Same as above
MPA-ER64	IIa	N/A	Same as above
MPAS-ER16	IIa	N/A	Same as above
MPAS-ER64	IIa	N/A	Same as above
MP-ER16	IIa	N/A	Same as above
MP-ER64	IIa	N/A	Same as above
NM-EC	IIa	N/A	Same as above
NRS2-EC	IIa	N/A	Same as above
NRS2-ECM	IIa	N/A	Same as above
NRS2-ER10	IIa	N/A	Same as above
TEP-ER10	IIa	N/A	Same as above
TEQ-ER10	IIa	TEQ/Model:TEQ-E10R	Same as above
VM-ER4	IIa	VM/Model:VM-E4R	Same as above
Ti-Max	IIa	N/A	Same as above
S-Max (SG20 + 1 model)	IIa	N/A	Same as above
Ti-Max (X-SG20ML + 1 model)	IIa	N/A	Same as above
S200EL	IIa	N/A	Same as above
SGM-ER16i	IIa	N/A	Same as above
SGM-ER20i	IIa	N/A	Same as above
SGMS-ER20i	IIa	N/A	Same as above
SGS-ES	IIa	N/A	Same as above
SGS-E2S	IIa	N/A	Same as above
SGA-E2S	IIa	N/A	Same as above
SGA-ES	IIa	N/A	Same as above
Ti-Max (X-SG65L + 1 model)	IIa	N/A	Same as above
Ti-Max (Z-SG45L + 1 model)	IIa	N/A	Same as above
Ti-Max	IIa	N/A	Same as above
Ti-Max (X-SG93 + 1 model)	IIa	N/A	Same as above
SGX-E20R	IIa	N/A	Same as above
FX (FX205m M4 + 4 models)	IIa	N/A	Same as above
S-Max	IIa	N/A	Same as above
Ti-Max	IIa	N/A	Same as above
AE	IIa	Air Motor AE Set/Model:AE SET	Same as above
VIVA ace	IIa	N/A	Same as above
OPTIMA (BA520FM + 1 model)	IIa	N/A	Same as above
BA45E	IIa	N/A	Same as above
BA25E	IIa	N/A	Same as above
BA66E	IIa	N/A	Same as above
BA65E	IIa	N/A	Same as above
BA175E	IIa	N/A	Same as above
BA280L	IIa	N/A	Same as above
BA604E	IIa	N/A	Same as above
BA602E	IIa	N/A	Same as above
BA604ES	IIa	N/A	Same as above
BA604EL	IIa	N/A	Same as above
BA602ES	IIa	N/A	Same as above
NLX nano	IIa	N/A	Same as above
NLX	IIa	N/A	Same as above

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
NLZ (NLZ S230 + 2 models)	IIa	N/A	Same as above
NLZ	IIa	N/A	Same as above
iMD (iMD EU + 1 model)	IIa	N/A	Same as above
VIVAMATE G5	IIa	N/A	Same as above
ENDO-MATE TC2	IIa	N/A	Same as above
ENDO-MATE DT	IIa	N/A	Same as above
ENDO-MATE DT2	IIa	N/A	Same as above
iProphy	IIa	N/A	Same as above
SM3	IIa	N/A	Same as above
Straumann Surgical Motor Pro (Straumann Surgical Motor Pro EU Q + 1 model)	IIa	N/A	Same as above
Ti-Max (X57 + 1 model)	IIa	N/A	Same as above
FX (FX57 + 1 model)	IIa	N/A	Same as above
AR-ER10(S)	IIa	N/A	Same as above
AR-EC(S)	IIa	N/A	Same as above
AR-ECM(S)	IIa	N/A	Same as above
AR-ER4(S)	IIa	N/A	Same as above
AR-ER4M(S)	IIa	N/A	Same as above
AR-EC(K)	IIa	N/A	Same as above
AR-ECM(K)	IIa	N/A	Same as above
Ti-Max (X55 + 1 model)	IIa	N/A	Same as above
EVA-ER4	IIa	N/A	Same as above
EVA-ER4M	IIa	N/A	Same as above
Ti-Max (S970 + 3 models)	IIa	N/A	Same as above
AS2000 B2/3	IIa	N/A	Same as above
AS2000 M4	IIa	N/A	Same as above
Varios Combi Pro	IIa	N/A	Same as above
Prophy-Mate neo (PMN-PTL-HP + 7 models)	IIa	N/A	Same as above
SGO2-E	IIa	N/A	Same as above
SGR2-E	IIa	N/A	Same as above
SGT2-E	IIa	N/A	Same as above
VA970(230V)	IIa	Varios 970/Model:Varios 970	Same as above
VA970 230V S1	IIa	Varios 970/Model:Varios 970	Same as above
VA970 230V	IIa	Varios 970/Model:Varios 970	Same as above
VA970 LUX 230V	IIa	Varios 970 LUX/Model:Varios 970 LUX	Same as above
VA970 LUX 230V S1	IIa	Varios 970 LUX/Model:Varios 970 LUX	Same as above
VA170 BEL SET	IIa	Varios 170/Model:Varios 170	Same as above
VA170S8	IIa	Varios 170/Model:Varios 170	Same as above
VA170 BEL SET2	IIa	Varios 170/Model:Varios 170	Same as above
VA170S5	IIa	Varios 170/Model:Varios 170	Same as above
VA170S1	IIa	Varios 170/Model:Varios 170	Same as above

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
VA170S2	IIa	Varios 170/Model:Varios 170	Same as above
VA170LUXS5	IIa	Varios 170 LUX/Model:Varios 170 LUX	Same as above
VA170LUXS1	IIa	Varios 170 LUX/Model:Varios 170 LUX	Same as above
VA170LUX BEL SET	IIa	Varios 170 LUX/Model:Varios 170 LUX	Same as above
VA170LUXS8	IIa	Varios 170 LUX/Model:Varios 170 LUX	Same as above
VA170LUX BEL SET2	IIa	Varios 170 LUX/Model:Varios 170 LUX	Same as above
VA170LUXS2	IIa	Varios 170 LUX/Model:Varios 170 LUX	Same as above
VA170LUXS4	IIa	Varios 170 LUX/Model:Varios 170 LUX	Same as above
VA370(230V)	IIa	Varios 370/Model:Varios 370	Same as above
VA370	IIa	Varios 370/Model:Varios 370	Same as above
VA370 LUX (230V)	IIa	Varios 370 LUX/Model:Varios 370 LUX	Same as above
VA370 LUX	IIa	Varios 370 LUX/Model:Varios 370 LUX	Same as above
VarioSurg 3(230V)	IIa	N/A	Same as above
VarioSurg 3(230V) Non FT	IIa	N/A	Same as above
VarioSurg 3（230V)AU	IIa	N/A	Same as above
Air Scaler Tip (S1 + 2 models)	IIa	N/A	Same as above
Air Scaler Tip (S10 + 3 models)	IIa	N/A	Same as above
Air Scaler Tip (S35 + V-P10 + 3 models)	IIa	N/A	Same as above
Air Scaler Tip (S65D +9 models)	IIa	N/A	Same as above
Air Scaler Tip (S75 + V-U15 + 4 models)	IIa	N/A	Same as above
FLASH pearl	IIa	N/A	Same as above
Varios Tip (G1 + 16 models)	IIa	G1/Model:G1 G2/Model:G2 G3/Model:G3 G4/Model:G4 G5/Model:G5 G6/Model:G6 G8/Model:G8 G9/Model:G9 G11/Model:G11 G12/Model:G12 G13/Model:G13 G16/Model:G16 G1-E/Model:G1-E	Same as above

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
		G2-E/Model:G2-E G3-E/Model:G3-E G4-E/Model:G4-E G6-E/Model:G6-E	
Varios Tip (P1 + 20 models)	IIa	P1/Model:P1 P1D/Model:P1D P2D/Model:P2D P3D/Model:P3D P10/Model:P10 P11L/Model:P11L P11R/Model:P11R P20/Model:P20 P21L/Model:P21L P21R/Model:P21R P25L/Model:P25L P25R/Model:P25R P26L/Model:P26L P26R/Model:P26R P40/Model:P40 P41/Model:P41 P20-E/Model:P20-E P21L-E/Model:P21L-E P21R-E/Model:P21R-E P25L-E/Model:P25L-E P25R-E/Model:P25R-E	Same as above
Varios Tip (V10 + V-P10 + 5 models)	IIa	V10/Model:V10 V-P10/Model:V-P10 V-P11R/Model:V-P11R V-P11L/Model:V-P11L V-P12/Model:V-P12 V-P26R/Model:V-P26R V-P26L/Model:V-P26L	Same as above
Varios Tip (G61D + 11 models)	IIa	G61D/Model:G61D G62D/Model:G62D G65D/Model:G65D G66D/Model:G66D G67D/Model:G67D G68D/Model:G68D V30/Model:V30 V-G70/Model:V-G70 V-G71/Model:V-G71 V-G72/Model:V-G72 V-G75/Model:V-G75 V-G76/Model:V-G76 G95/Model:G95	Same as above
Varios Tip (V30 + V-G77 + 2 models)	IIa	V30/Model:V30 V-G77/Model:V-G77 V-G78/Model:V-G78 V-G79/Model:V-G79	Same as above
Varios Tip (E30LD + 3 models)	IIa	E30LD/Model:E30LD E30RD/Model:E30RD E31D/Model:E31D E32D/Model:E32D	Same as above
VarioSurg Tip (SG1A + 20 models)	IIa	N/A	Same as above
VarioSurg Tip (SCL1 + 5 models)	IIa	SCL1/Model:SCL1 SCL3/Model:SCL3 SCL5/Model:SCL5	Same as above

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
		SG9/Model:SG9 SG10/Model:SG10 SG11/Model:SG11	
VarioSurg Tip (SG17 + 2 models)	IIa	SG17/Model:SG17 SG18R/Model:SG18R SG18L/Model:SG18L	Same as above
VarioSurg Tip	IIa	G1-S/Model:G1-S	Same as above
VarioSurg Tip (V10-S + V-P10 + 3 models)	IIa	V10-S/Model:V10-S V-P10/Model:V-P10 V-P11R/Model:V-P11R V-P11L/Model:V-P11L V-P12/Model:V-P12	Same as above
VarioSurg Tip (E30LD-S + 3 models)	IIa	E30LD-S/Model:E30LD-S E30RD-S/Model:E30RD-S E31D-S/Model:E31D-S E32D-S/Model:E32D-S	Same as above
VarioSurg Tip (P20-S + 2 models)	IIa	P20-S/Model:P20-S P25R-S/Model:P25R-S P25L-S/Model:P25L-S	Same as above
VarioSurg Tip (SCL1D + 10 models)	IIa	SCL1D/Model:SCL1D SCL2D/Model:SCL2D SCL3D/Model:SCL3D SCL4D/Model:SCL4D SCL5D/Model:SCL5D SG15A/Model:SG15A SG15B/Model:SG15B SG15C/Model:SG15C SG15D/Model:SG15D SG16A/Model:SG16A SG16B/Model:SG16B	Same as above
Varios Tip (E4 + 24 models)	IIa	E4/Model:E4 E4D/Model:E4D E7D/Model:E7D E8D/Model:E8D E15D/Model:E15D E9/Model:E9 E9D/Model:E9D E14D/Model:E14D E11/Model:E11 E12/Model:E12 U files 33mm ISO 15/Model:U files 33mm ISO 15 U files 33mm ISO 20/Model:U files 33mm ISO 20 U files 33mm ISO 25/Model:U files 33mm ISO 25 U files 33mm ISO 30/Model:U files 33mm ISO 30 U files 33mm ISO 35/Model:U files 33mm ISO 35 V30/Model:V30	Same as above

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
		V-S50/Model:V-S50 V-S51/Model:V-S51 V-S52/Model:V-S52 V-S53/Model:V-S53 V-S51D/Model:V-S51D V-S52D/Model:V-S52D V-S53D/Model:V-S53D	
SGO-1	IIa	N/A	Same as above
SGO-2	IIa	N/A	Same as above
SGO-3	IIa	N/A	Same as above
SGO-4	IIa	N/A	Same as above
SGO-5	IIa	N/A	Same as above
SGO-6	IIa	N/A	Same as above
Varios Tip (E5 + 3 models)	IIa	E5/Model:E5 E6/Model:E6 E7/Model:E7 E8/Model:E8	Same as above
iPex Ⅱ	IIa	N/A	Same as above
SGR-1	IIa	N/A	Same as above
SGR-2	IIa	N/A	Same as above
SGR-3	IIa	N/A	Same as above
SGT-1	IIa	N/A	Same as above
SGT-2	IIa	N/A	Same as above
pico bur (PC1 + 9 models)	IIa	N/A	Same as above
iSD900	IIa	N/A	Same as above
Straumann Surgical Motor Pro 2	IIa	N/A	Same as above
smartGun ONE (SGO-KV + 1 model)	IIa	N/A	Same as above
smartGun PERIO (SGP-KV + 1 model)	IIa	N/A	Same as above

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive: N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/22	NAKANISHI_CL607_2024-05-22	Initial issue