

EC DECLARATION OF CONFORMITY**MANUFACTURER**

NAKANISHI INC.
700 Shimohinata, Kanuma, Tochigi 322-8666, Japan

AUTHORIZED EU REPRESENTATIVE

NSK EUROPE GmbH
Elly-Beinhorn-Strasse 8, 65760 Eschborn, Germany

MEDICAL DEVICE

General Product Group Name:

Remotely-driven dental drilling system motor

Product Name: Ti-Max NLX nano
Model: See No.000028-85-06 004 Attachment
Order Code: See No.000028-85-06 004 Attachment
Classification: Class IIa (Rule9)
Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg, Germany
Notified Body number: 0197

NAKANISHI INC. is exclusively responsible for the Declaration of Conformity.
The serial number applied to this product is managed by the "Shipping history data".
This Declaration of Conformity is valid for a definite number of manufactured products.

The undersigned hereby declares that the medical device, as specified above, conforms with the essential requirements listed in Annex I of EC Directive 93/42/EEC.

The Declaration of Conformity is based on the EC Directive 93/42/EEC Annex II, excluding Section 4. The Declaration of Conformity is issued under the supervision of TÜV Rheinland LGA Products GmbH, approving the conformity of Annex II Section 3 requirements, with reference to articles 1 and 3 of directive 93/42/EEC.

EC Certificate Registration No.: HD 60148508 0001
This Declaration of Conformity is valid until 2024-05-26.

And, this Declaration of Conformity includes the EC Directive 2006/42/EC.

Tochigi, Japan: 2021-11-09
Date


Masaaki Kikuchi,
Management Representative

Type: Ti-Max NLX nano

Model : Ti-Max NLX nano

Order Code : Y1001362

Y1001362:No.1-No.5

No.	Component name	Component model	Order Code
1	NLX nano U Control Unit	NLX nano U	U1062002
2	AC Cord for 230V	Power Cord (230V)	U439550
3	AC Adapter for 230V	—	U499001
4	NLX nano Motor	NLX nano	E1044051
5	NLX CD Motor Cord	NLX CD	E1044061
6	AC Cord for 100V	—	U435550
7	AC Cord for 120V	—	U438550
8	AC Adapter for 100V	NLAC(100V)	U497001
9	AC Adapter for 120V	—	U498001
10	nano CDB (Short rear cover type)	nano CDB	E1044066
11	nano LCDB (Long rear cover type)	nano LCDB	E1044067
12	NLX BF without case	NLX BF D1C0B	U1020010
13	NLX BF with case	NLX BF D1C0	U1020011
14	NLS-A ADP without case	NLS-A ADPB	U1020051
15	NLS-A ADP with case	NLS-A ADP	U1020050
16	NLS-A SEL without case	NLS-A SELB	U1020056
17	NLS-A SEL with case	NLS-A SEL	U1020055
18	Multi Pad (Manual selection type)	MP01	U1018001
19	Multi Pad (Manual selection type with angle plate)	MPS01	Y1001845
20	Multi Pad (Auto selection type)	MP02	U1018002
21	Multi Pad (Auto selection type with angle plate)	MPS02	Y1001846
22	Harness for Motor Junction	LEAD CONNECTOR	U522057
23	Harness for LED Junction	LEAD CONNECTOR	U522058
25	Harness for Motor Switching	LEAD CONNECTOR	20000907
26	Harness for External Interface	LEAD CONNECTOR	20000903
27	Harness for RS-232C communication	LEAD CONNECTOR	20000902
28	Harness for CAN communication	LEAD CONNECTOR	20000906

No.	Accessory name	Accessory model	Order Code
1	Tube set		
	TUBE RETAINER C	—	U427711
	MINI FITTING	—	U522300
	TUBE A	—	U522560
2	AC CAP	—	20001300
3	PROTECTION PLUG	SG50LED	10001595