

EU DECLARATION OF CONFORMITY (MDR)**MANUFACTURER**

NAKANISHI INC.
700 Shimohinata, Kanuma, Tochigi 322-8666, Japan
Single Registration Number(SRN): JP-MF-000011271
Registered Trade Name: NAKANISHI INC.
Registered Trade Mark: NSK

AUTHORIZED EU REPRESENTATIVE

NSK EUROPE GmbH
Elly-Beinhorn-Strasse 8, 65760 Eschborn, Germany
Single Registration Number(SRN): DE-AR-000007040

MEDICAL DEVICE

EMDN Description:	DENTAL PROPHYLAXIS EQUIPMENT
EMDN Code	Z12119007
Basic UDI-DI:	45602249800001457C
UDI-DI:	See No.A10100-51-07-001 000 Attachment 1
Product and Trade Name:	Varios Combi Pro2 etc. See No.A10100-51-07-001 000 Attachment 1
Model:	See No.A10100-51-07-001 000 Attachment 1
Order Code:	See No.A10100-51-07-001 000 Attachment 1
Classification:	Class IIa, Rule 9
Common Specifications (CS):	N/A
Intended Purpose :	The dental device is intended for the following application(s): [Tooth Polishing System] Removal of supragingival and subgingival accretions and deposits, and accretions and deposits on prostheses (including implants). [Ultrasonic Scalers] Removal of accretions and deposits from the surface of teeth and dental restorations (fillings and prostheses), finishing (preparation and adjustment/polishing), removal and cleaning of infected dental tissues, and root canal enlargement.
GSPR(MDR Annex I):	A10100-41-40-001
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystrasse 2, 90431 Nürnberg, Germany
Notified Body number:	0197

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

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 device that is covered by the present declaration is in conformity with the EU Regulation 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU Declaration of Conformity.

The Declaration of Conformity is based on the EU Regulation 2017/745 Annex IX.

EU Certificate Registration No.: HZ 2002410-1

This Declaration of Conformity is valid until 2027-06-14

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

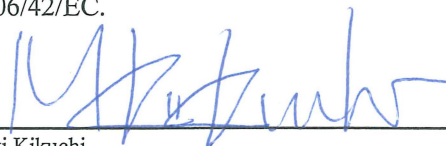
Tochigi, Japan:

Place, Date

2025.2.28

Masaaki Kikuchi,

Person Responsible for Regulatory Compliance



No.	Product Name and Trade Name	Model	Order Code	UDI-DI
1	Varios Combi Pro2	NE355	UA1421-0001	N/A
2	FOOT CONTROL WIRELESS	FC-83	ZF16020001	04560264579514
3	Powder Handpiece(For Prophy use)	Powder Handpiece(For Prophy use)	T1074001	04560264548459
4	Powder Handpiece(For Perio use)	Powder Handpiece(For Perio use)	T1077001	04560264548473