

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:	VARIOUS DENTAL STOMATOLOGY INSTRUMENTS
EMDN Code	Z121190
Basic UDI-DI:	456022498000021578
UDI-DI:	See No.A09900-51-07-001 000 Attachment
Product and Trade Name:	VarioSurg 4
Model:	See No.A09900-51-07-001 000 Attachment
Order Code:	See No.A09900-51-07-001 000 Attachment
Classification:	Class IIa (Rule9)
Common Specifications (CS):	N/A
Intended Purpose:	Removal of accretions and deposits from the surface of teeth and dental restorations (fillings and prostheses), root canal preparation for retrograde endodontics (including removal of root canal filling materials), cutting, removal, incision, and perforation of jawbones, detachment of periodontal membrane due to tooth extraction, and detachment of mucosal membrane due to implant surgery.
GSPR(MDR Annex I):	No.A09900-41-40-001
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. The Declaration of Conformity is issued under the supervision of TÜV Rheinland LGA Products GmbH, approving the conformity of Annex IX of EU Regulation 2017/745.
 EU Certificate Registration No.: HZ 2002410-1
 This Declaration of Conformity is valid until 2027-04-19
 And, this Declaration of Conformity includes the EC Directive 2006/42/EC.

Tochigi, Japan: 2024-06-13
 Place, Date

Masaaki Kikuchi
 Person Responsible for Regulatory Compliance

Model: VarioSurg 4 EU
Product Code: Y1500772

Component

No.	Component Name	Component Model	Order Code	DI Code
1	VarioSurg 4 Control Unit	NE356	—	04589551388431
2	FOOT CONTROL WIRELESS	FC-86	ZF16040001	04589551389230
3	VS4-LED-HPSC	VS4-LED-HPSC	EA14170001	04589551389247