EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2002410-1
Manufacturer:	Nakanishi Inc. 700 Shimohinata, Kanuma, Tochigi 322-8666 Japan
EUDAMED Single Registration No.:	JP-MF-000011271
Products:	Products of class IIa: Z121101 - INSTRUMENTS FOR DENTAL TREATMENT UNITS Z121190 - VARIOUS DENTAL STOMATOLOGY INSTRUMENTS Q010104 - DENTAL PROCEDURE DEVICES - VARIOUS Q010599 - DENTAL INSTRUMENTS, SINGLE-USE - OTHER
Authorized representative(s):	NSK EUROPE GmbH Elly-Beinhorn-Strasse 8, 65760 Eschborn, Germany

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	150279330-357
Effective date:	2024-09-10
Expiry date:	2027-06-14
Issue date:	2024-09-10

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-MDR-091

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700 Shimohinata,
Kanuma, Tochigi
322-8666 Japan

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2022-06-15
1	Added product (Z121190)	2022-09-29
2	Added product (Q010104)	2023-03-27
3	Added product (Q010599), changed Expiry date to 2027-06-14	2024-09-10

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