

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 623882
Issued To: **NSK Europe GmbH**
Elly-Beinhorn-Straße 8
65760 Eschborn
Germany

In respect of:

Design and manufacture of automated reprocessing devices for dental instruments.

Auslegung und Herstellung von Reinigungs- und Desinfektionsgeräten für Dental-Instrumente.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-06-19**

Date: **2020-03-16**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 623882

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NBOG Code(s)	Device Description	Intended purpose per IFU
Class IIb		
MD 1107 SMD 7010	Automated reprocessing device performing the decontamination of dental instruments	Automated reprocessing device performing the necessary steps of decontamination and maintenance prior to sterilization. Intended to purge, clean, disinfect and lubricate dental handpieces defined as rotating instruments such as straight handpieces, contra angles and turbines. Device should be used only with pre-cleaned dental handpieces.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Canon Bretagne SAS Les Landes de Beaugé Liffre Cedex 35341 France	Manufacture
Nakanishi Inc. 700 Shimohinata, Kanuma Tochigi, 322-8666 Japan	Design

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Certificate History

Certificate No: **CE 623882**
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Date	Reference Number	Action
19 June 2016	8471960	First issue. Transfer from another Notified Body.
19 February 2019	8814542	Traceable to NB 0086.
Current	3141334	Certificate renewal. Addition of product table.

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