By Royal Charter

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **19 June 2016** Date: **19 June 2016** Expiry Date: **14 July 2020**

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

List of Significant Subcontractors

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

Certificate No:	**CE 623882**
Date:	**19 June 2016**
Issued To:	**NSK Europe GmbH** **Elly-Beinhorn-Straße 8** **65760 Eschborn** **Germany**

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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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 623882**

Date: **19 June 2016**

Issued To: **NSK Europe GmbH**
Elly-Beinhorn-Straße 8
65760 Eschborn
Germany

Date	Reference Number	Action
19 June 2016	8471960	First issue. Transfer from another Notified Body.

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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.