

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number:

MD 623878

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2016-06-15

Latest Revision Date: 2024-06-17

Effective Date: 2024-07-15

Expiry Date: 2027-07-14



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Certificate No: MD 623878

## Registered Scope:

Design and Development, Manufacture, Sales and Service of active automated decontamination dental device performing automated reprocessing and maintenance of soiled rotary dental handpieces and dental instruments prior sterilization.

Service, Distribution and Sale of goods for resale of the following applications:

Dental:

rotary cutting instruments; ultrasonic instruments; surgical rotary cutting instruments; Prophylaxis powders; Cleaning solution; Disinfecting solution; Irrigation lines; Lubricant for Dental Instruments / Panaspray: Various Dental Stomatology instruments and active automated Cleaning and disinfection equipment.

Surgery:

rotary cutting instruments; sterile burs; wire pin driver.

Konzeption und Entwicklung, Herstellung, Vertrieb und Wartung aktiver automatischer Reinigungs- und Desinfektionsgeräte, welche eine automatisierte Wiederaufbereitung und Pflege verschmutzter rotierender Dentalhandstücke und dentaler Instrumente vor der Sterilisation durchführen.

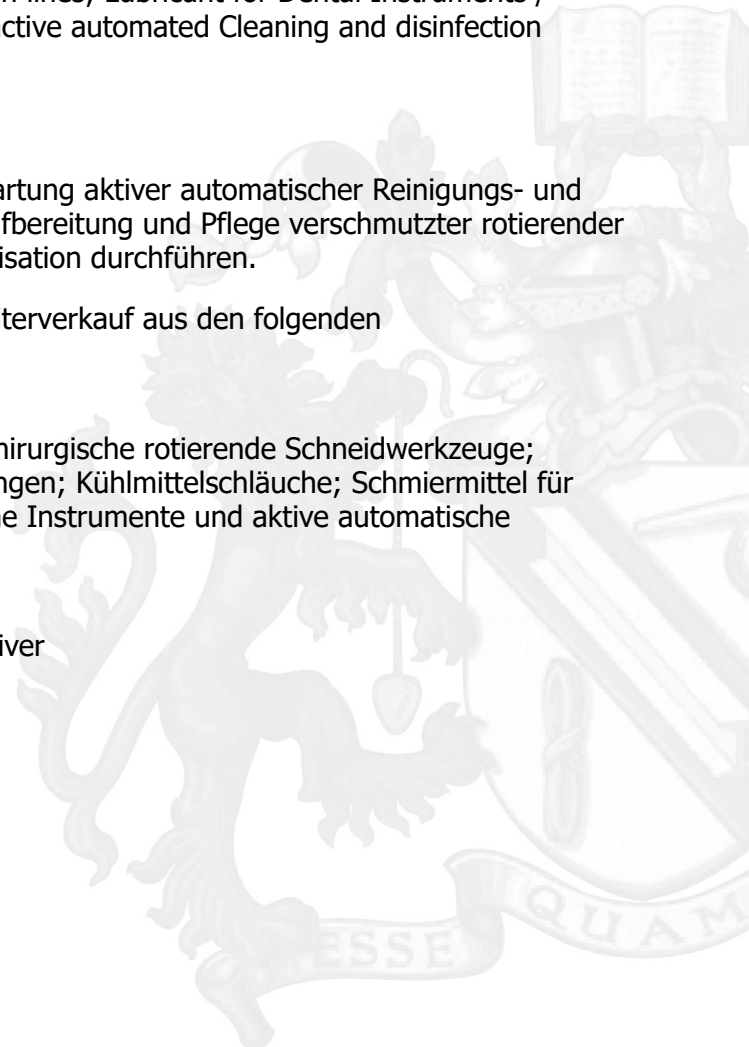
Wartung, Distribution und Vertrieb von Waren für den Weiterverkauf aus den folgenden Anwendungsbereichen:

Dental:

Rotierende Schneidwerkzeuge; Ultraschall-Instrumente; chirurgische rotierende Schneidwerkzeuge; Prophylaxepulver; Reinigungslösungen; Desinfektionslösungen; Kühlmittelschläuche; Schmiermittel für Dentalinstrumente / PanaSpray; diverse dentalmedizinische Instrumente und aktive automatische Reinigungs- und Desinfektionsgeräte

Chirurgie:

Rotierende Schneidwerkzeuge; sterile Bohrer; Wire Pin Driver



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

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

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