By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 575415**

Issued To: **Geuder AG**
Hertzstraße 4
69126 Heidelberg
Germany

In respect of:

See certificate scope page.

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: **2016-06-29** Date: **2019-05-28** Expiry Date: **2024-05-25**

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Certificate No: CE 575415

Certificate Scope:

Design, development and manufacture of devices for ophthalmology: Ultrasonic Handpieces; Single-Use Light Conductors / Fiber Optics, sterile; Fiber Optic Instruments, reusable; Single-Use Accessory Kits with Ultrasonic Tips, sterile; Ultrasonic tips, reusable; Single-Use Vitrectomy Instruments, sterile; Single-Use DMEK Cartridge, sterile; Single-Use-DMEK-Transportation Cartridge; Sclera Pins; Single-Use Iris Retractor, sterile; Vitrectomy Infusion Tube and Cutting Heads; Single-Use Trocar System, sterile; Single-Use Ophthalmic Cannula; Injection-/Infusion Tubing; Single-Use Tubing Sets, sterile; Tubing Sets, reusable; Cassettes; Single use vitreous cutters, sterile; Single-Use Vitrectors, sterile; Single-use LED Lightsource, sterile.
Those aspects of Annex II related to sterility in the design, development and manufacture of devices for ophthalmology: Single-Use Adapters, sterile; I/A Instruments, sterile.

Auslegung, Entwicklung und Herstellung von Produkten für die Ophthalmologie: Ultraschallhandgriffe; Einmal-Lichtleiter, steril; Kaltlichtinstrumente, wiederverwendbar; Einmal-Kits mit Ultraschallspitzen, steril; Ultraschallspitzen, wiederverwendbar; Einmal-Vitrektomiespitzen, steril; Einmal-DMEK-Kartusche, steril; Einmal-DMEK-Transportkartusche, steril; Skleranägel; Einmal-Irisretraktor, steril; Vitrektomie Infusionsrohr und Schneideköpfe; Einmal-Trokarsystem, steril; ophthalmologische Einmal-Kanülen; Injektions- / Infusionshalterungen; Einmal-Schlauchsysteme, steril; Schlauchsysteme, wiederverwendbar; Kassetten; Einmal-Vitrektoren, steril; Einmal-LED Lichtquellen, steril.
Die Aspekte des Anhangs II im Zusammenhang mit der Sterilität bei der Auslegung, Entwicklung und Herstellung von Einmal-Adaptern für Glasspritzen, steril; Spül- und Sauginstrumenten, steril.

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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 575415

Issued To:

Geuder AG
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Number	Device Name	Intended purpose per IFU
Class IIb		
MD 1105	Ultrasonic Handpieces	Used with ultrasound tips to perform phacoemulsification, a surgical procedure that uses ultrasonic energy to fragment (or emulsify) a cataractous lens and removes the lens material through a small incision.
Class IIa		
MD 0105	Single-use Light Conductors / Fiber Optics, sterile	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.
MD 0105	Single-use Light Conductors / Fiber Optics, sterile, incl. Uno Colorline	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.

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Number	Device Name	Intended purpose per IFU
MD 0105	Fiber Optic Instruments, reusable	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.
MD 0105	Single-use Accessory Kits with Ultrasonic Tips, sterile	Accessories and tips to be used with US-handpieces to perform phacoemulsification.
MD0105	Ultrasonic tips, reusable	US tips to be used with US-handpieces to perform phacoemulsification.
MD 0105	Single-use Vitrectomy Instruments Uno Colorline, sterile	For manipulation and crushing of intraocular tissue during pars plana vitrectomy. For usage in the posterior eye segment for cutting and gripping of ocular structures.
MD 0102	Single-use DMEK Cartridge, sterile	Used for Descemet Membrane Endothelial Keratoplasty, a special technique for corneal transplantation. For uploading and injecting descemet membrane transplant.
MD 0102	Single-use DMEK Transportation Cartridge, RAPID	Used for Descemet Membrane Endothelial Keratoplasty, a special technique for corneal transplantation. For uploading, transporting and injecting descemet membrane transplant.

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Number	Device Name	Intended purpose per IFU
MD 0105	Sclera Pins	To be used to occlude temporarily the exterior points of access (incisions) during surgeries in the posterior segment to minimize leakages of liquid or gases.
MD 0105	Single-use Iris Retractor, sterile	To be used dilate the iris mechanically.
MD 0105	Mega-Vit Vitrectomy Infusion Tube and Cutting Heads	Accessories to use with high speed drive for cutting and intraocular removal of the vitreous body.
MD 0105	Single-use Trocar System Uno Colorline, sterile	To open and keep the scleral incision (in the area of pars plana) in open state, so to allow access of different ophthalmic surgical instruments to the inside of the eye.

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Number	Device Name	Intended purpose per IFU
MD 0102	Single-use Ophthalmic Cannula	Used to supply or remove liquids such as saline solution (BSS), viscous liquids, PFCL, air or gases. Capsule polishing needles or vacuum cleaner needles with silicone tip can also be used to remove tissue or materials.
MD 0102	Injection/Infusion Tubing	Infusion Tubing: applying liquids and air. Injection tubing: applying viscous solutions into eyes in vitreoretinal surgery.
MD 0102	Single-use Tubing Sets, sterile	Irrigation and aspiration of aqueous solutions, air injections and silicone oil into the eye.
MD 0102	Tubing Sets, reusable	For irrigation and aspiration of aqueous solutions, air injections and silicone oil into the eye.
MD 0102	Cassettes	Connected to the ophthalmic system for irrigation and aspiration.
MD 1105	Single-use vitreous cutters, sterile	For removal of vitreous body from the eye.

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Number	Device Name	Intended purpose per IFU
MD 1105	Single-use Vitrectors, sterile, Uno Colorline	For removal of vitreous body from the eye.
MD 1105	OcuLED Single-use LED Lightsource, sterile	For endoillumination during ocular surgery.
Class Is		
MD 0105	Single-use Adapters, sterile	Used during the pneumatic injection of silicone oil into the eyes of patients. It is a protective holder for the glass syringes which are filled with silicone oil or viscous fluids. It is to prevent injuries in case the glass syringe breaks under the pressure.
MD 0102	I/A Instruments, sterile	Used in ophthalmological surgery, to remove liquids and tissue from the eye and irrigate the eye with air or balanced saline solution (BSS).

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 575413**

Issued To: **Geuder AG**
Hertzstraße 4
69126 Heidelberg
Germany

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2016-06-29** Date: **2019-05-24** Expiry Date: **2024-05-25**

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Certificate No: CE 575413

Certificate Scope:

Manufacture of ophthalmic Single-Use Light Conductors / Fiber Optics, sterile; Single-Use Ophthalmic Cannula, sterile; Single-Use Tubing Sets, sterile; Irrigation/Aspiration (I/A) Instruments, sterile; Single-use Endo-probes, sterile; Single-use Knives, sterile; Single-use Trephines, sterile.
Those aspects of Annex V related to sterility in the manufacture of Bonn Injection Sets for ophthalmology.
Those aspects of Annex V related to metrology in the manufacture of ophthalmic surgical measuring devices.

Herstellung von ophthalmologischen Einmal-Lichtleitern, steril; ophthalmologischen Einmal-Kanülen, steril; Einmal-Schlauchsystemen, steril; Spül- und Sauginstrumenten, steril; Einmal-Endosonden, steril; Einmal-Messern steril; Einmal-Trepanen, steril.
Die Aspekte des Anhangs V im Zusammenhang mit der Sterilität bei der Produktion Bonner Injektonssets, steril.
Die Aspekte des Anhangs V im Zusammenhang mit der Messfunktion bei der Produktion der ophthalmologischen Messinstrumente.

First Issued: **2016-06-29** Date: **2019-05-24** Expiry Date: **2024-05-25**

EC Certificate - Production Quality Assurance

Supplementary Information to CE 575413

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0105	Single-use Light Conductors / Fiber Optics, sterile	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.
MD 0102	Single-use Ophthalmic Cannula, sterile	Used to supply or remove liquids such as saline solution (BSS), viscous liquids, PFCL, air or gases. Capsule polishing needles or vacuum cleaner needles with silicone tip can also be used to remove tissue or materials.
MD 0102	Single-use Tubing Sets, sterile	Irrigation and aspiration of aqueous solutions, air injections and silicone oil into the eye.
MD 0102	Irrigation/Aspiration (I/A) Instruments, sterile	Used in ophthalmological surgery, to remove liquids and tissue from the eye and irrigate the eye with air or balanced saline solution (BSS).
MD 0105	Single-use Endoprobes Uno Colorline, sterile	To direct and localize the transmission of laser output energy to the operative site in the ophthalmic surgical field. The laser is used to finely coagulate ocular tissue.

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 575413

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0105	Single-use Knives, sterile	To make surgical cuts in ophthalmological surgery.
MD 0105	Single-use Trephines, sterile	Used for preparing the donor cornea for transplantation.
Class Is		
MD 0105	Bonn Injection Set, sterile	Used to inject medications intravitreally. The medications do not come with the set.
Class Im		
MD 0104	Measuring Instruments	Instruments for length and angle measurements in ophthalmology.

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Certificate of Registration

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

This is to certify that:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Holds Certificate Number: **MD 575412**

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-06-27
Latest Revision Date: 2020-05-18

Effective Date: 2020-05-26
Expiry Date: 2023-05-25

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Certificate No: **MD 575412**

Registered Scope:

Design, development, manufacture, warehousing, distribution, installation and maintenance of active and non active, sterile and non sterile ophthalmic surgical devices/systems, instruments and accessories, ophthalmic implants, sterilization trays and containers.
Warehousing and distribution of silicone oils, dyes, perfluorocarbons and semifluorinated alkanes for use as liquid intraocular endotamponades and gas-based intraocular tamponades and vitreous substitutes for the area of ophthalmology.
Auslegung, Entwicklung, Produktion, Lagerhaltung, Vertrieb, Installation und Instandhaltung von aktiven und nicht aktiven, sterilen und nicht sterilen ophthalmo-chirurgischen Geräten/Systemen, Instrumenten und Zubehör, ophthalmologischen Implantaten, Sterilisationsbehältern und Sterilisationscontainern.
Lagerhaltung und Vertrieb von Silikonölen, Färbemitteln, Perfluorcarbonverbindungen und semiflourierten Alkanen für die Verwendung als flüssige intraokulare Endotamponaden, gasförmige intraokulare Tamponaden und Glaskörperersatzstoffe im Einsatzbereich der Ophthalmologie.

Original Registration Date: 2016-06-27
Effective Date: 2020-05-26
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Expiry Date: 2023-05-25