

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: **2020-08-10**

Expiry Date: **2024-05-25**

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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.

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, sterile; 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; Single-Use Silicone Implants, 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-Irisretractor, 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; Einmal-Silikonimplantate, steril.

Die Aspekte des Anhangs II im Zusammenhang mit der Sterilität bei der Auslegung, Entwicklung und Herstellung von Einmal-Adaptoren für Glasspritzen, steril; Spül- und Sauginstrumenten, steril.

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Supplementary Information to CE 575415

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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.
MD 0105	Single-use Silicone Implants, sterile	For use on the sclera to aid in retinal reattachment.
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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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.

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Number	Device Name	Intended purpose per IFU
Class IIa		
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.
MD 0105	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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Class IIa		
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
Class IIa		
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
Class IIa		
MD 1105	Single-use Vitrectors, sterile, Uno Colorline	For removal of vitreous body from 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 that 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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