

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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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.

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.

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.

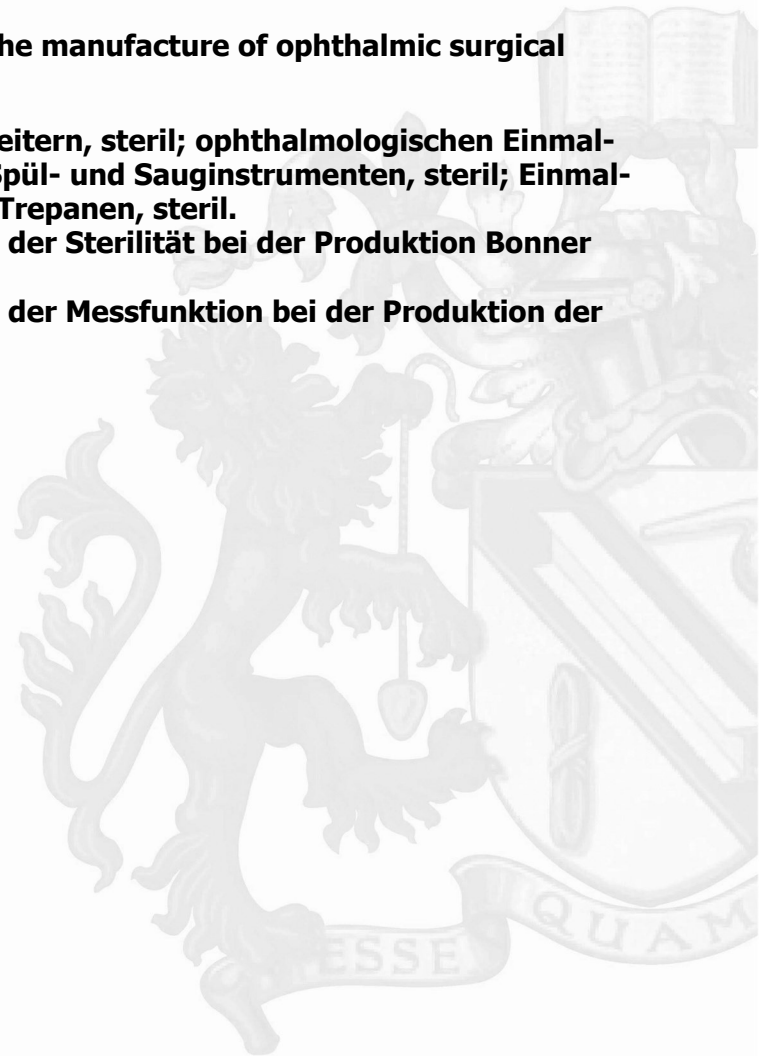
Those aspects of Annex V related to sterility in the manufacture of Bonn Injection Sets for ophthalmology.

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 Injektionssets, steril.

Die Aspekte des Anhangs V im Zusammenhang mit der Messfunktion bei der Produktion der ophthalmologischen Messinstrumente.

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Supplementary Information to CE 575413

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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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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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