By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 711665**

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

In respect of:

Design, development and manufacture of active, non sterile ocular electrosurgical coagulation devices.
Auslegung, Entwicklung und Produktion von aktiven, nicht sterilen okularen elektrochirurgischen Koagulationsinstrumenten.

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: **2020-05-15** Date: **2020-05-15** Expiry Date: **2024-05-26**

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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.

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Supplementary Information to CE 711665

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NBOG Code	Device Name	Intended Purpose per IFU
Class IIb		
MD 1104 MD 1105 MD 1402	Diathermy Instruments	Used for electrosurgical coagulation of tissue and blood vessels during ophthalmic surgery.

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