bsi.

By Royal Charter

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **29 June 2016** Date: **29 June 2016** Expiry Date: **25 May 2019**

...making excellence a habit.™

bsi.

By Royal Charter

Certificate No: CE 575413

Certificate Scope:

Manufacture of non active, sterile and non sterile ophthalmic surgical products and accessories.

Produktion von nicht aktiven, sterilen und nicht sterilen ophthalmo-chirurgischen Produkten und Zubehör.

Those aspects of Annex V related to metrology in the manufacture of ophthalmic surgical measuring devices.

Die Aspekte des Anhangs V im Zusammenhang mit der Messfunktion bei der Herstellung der ophthalmo-chirurgischen Messinstrumente.

Those aspects of Annex V related to sterility in the manufacture of ophthalmic surgical irrigation/aspiration (I/A) instruments, single-use irrigation cannulas, single-use endoprobes, single-use fiber optics, single-use adapters for glass syringes and Bonn Injection Sets.

Die Aspekte des Anhangs V im Zusammenhang mit der Sterilität bei der Herstellung der ophthalmo-chirurgischen Spül- und Sauginstrumente, Einmal-Spülkanülen, Einmal-Endosonden, Einmal-Lichtleiter, Einmal-Adapter für Glasspritzen und Bonner Injektionssets.

First Issued: **29 June 2016** Date: **29 June 2016** Expiry Date: **25 May 2019**

...making excellence a habit.™

"TEHNOMEDICA" S.R.L. IDNO 1002600053266

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

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 13485:2003 & EN ISO 13485:2012 for the following scope:

Please see scope page.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-27
Latest Revision Date: 2017-05-16

Effective Date: 2017-05-26
Expiry Date: 2019-02-28

...making excellence a habit.™

"TEHNOMEDICA" S.R.L. IDNO 1002600053206

Certificate No: MD 575412

Registered Scope:

Design, development, manufacture and control of 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 und Lenkung der 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
Latest Revision Date: 2017-05-16

Effective Date: 2017-05-26
Expiry Date: 2019-02-28

"TEHNOMEDICA" S.R.L. IDNO 1002600053256

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Holds Certificate No: **FM 575411**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, development, manufacture, warehousing, distribution, installation and maintenance of ophthalmo-surgical instruments, active device systems and associated accessories, implants, sterilisation trays and containers.
Warehousing and distribution of gases, silicone oils, dyes, perfluorocarbons and semifluorinated alkanes for ophthalmology.

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2001-06-01
Latest Revision Date: 2018-09-14

Effective Date: 2017-05-26
Expiry Date: 2020-05-25

...making excellence a habit.™

"TEHNOMEDICA" S.R.L. IDNO 1002600053256

bsi.

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:

Design, development and manufacture of active and non active, sterile and non sterile ophthalmic surgical devices/systems, instruments, accessories and ophthalmic implants.

Auslegung, Entwicklung und Produktion von aktiven und nicht aktiven, sterilen und nicht sterilen ophthalmo-chirurgischen Geräten/Systemen, Instrumenten, Zubehör und ophthalmologischen Implantaten.

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **29 June 2016** Date: **29 June 2016** Expiry Date: **25 May 2019**

...making excellence a habit.™

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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK
A member of BSI Group of Companies.

"TEHNOMEDICA" S.R.L. IDNO 1002600052256