Certificate

EC-Certificate

(full quality assurance system)
according to annex II (excluding section 4) of
Medical Devices Directive 93/42/EEC

It is herewith confirmed by

BSI Group Deutschland GmbH
Eastgate, Hanauer Landstrasse 115
60314 Frankfurt am Main
Germany

in its function as Notified Body (0535), that the manufacturer:

Geuder®
Precision made in Germany

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

concerning the medical devices

ophthalmic surgical instruments and accessories
(products/variants specified in appendix)

fulfils the requirements according to Annex II (excluding section 4) Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the design, production and final inspection of the specified devices.
For the placing on the market of class III products an additional Annex II section 4 certificate is required.

The appendix is part of this certificate and contains 2 pages.

Report No.: SMO7955408
Certificate No.: CE 575415

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-248.10.04

First Issue Date:
May 28, 2004.

Based on periodical surveillance this certificate is valid until
May 25, 2019.

Current Issue Date: June 13, 2014

Certification Body

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Translation

Appendix of EC-Certificate

(full quality assurance system)
according to annex II (excluding section 4) of Medical Devices Directive 93/42/EEC
Certificate No.: CE 575415

Medical devices of the manufacturer:

Geuder®
Precision made in Germany

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Name of product	Variant	Item	UMDNS/ GMDN	Class
Megatron and Megatron S3 Pressure Sensor	*	*	17-596	IIb
Single-Use Retinal Tack	*	*	12-744	IIb
Single-Use DMEK Cartridge, sterile	*	*	16-755	IIa
Single-Use Injection / Infusion Tubing, sterile	*	*	10-573	IIa
Single-Use Iris Retractor, sterile	*	*	10-906	IIa
Single-Use Cannulae, sterile	*	*	17-899	IIa
Single-Use Light Conductors / Fiber Optics, sterile, incl. Uno Colorline	*	*	12-345	IIa
Single-Use Knives, sterile	*	*	15-226	IIa
Single-Use Silicone Implants for Retinal Detachment	*	*	17-165	IIb
Single-Use Vitrectomy Instruments Uno Colorline, sterile	*	*	15-621	IIa
Single-Use Trocar Systems Uno Colorline, sterile	*	*	15-260	IIa

* According to current product list.

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Frankfurt am Main, June 13, 2014

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Medical devices of the manufacturer:

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Name of product	Variant	Item	UMDNS/ GMDN	Class
Eye Spheres	*	*	17-165	IIb
Ruprecht Intubation Set	*	*	13-119	IIb
Injection-/Infusion Tubing	*	*	15-206	IIa
Fiber Optic Instruments	*	*	12-345	IIa
Single-Use Tubing Sets and Venturi Cassetts, sterile	*	*	15-277	IIa
Tubing Sets and Venturi Cassetts, reusable	*	*	15-277	IIa
Sclera Pins	*	*	15-876	IIa
Oggel Intubation Set	*	*	13-119	IIb
I/A Instruments	*	*	10-573	IIa

* According to current product list.

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