



Certificate

EC-Certificate

(Production quality assurance system)

according to annex V 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 (products/variants specified in appendix)

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

The appendix is part of this certificate and contains 1 page.

Report No.: SMO7955408

Certificate No.: CE 575413



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

Wilfried Babel
Certification Body



Appendix of EC-Certificate

(Production quality assurance system)

according to annex V of Medical Devices Directive 93/42/EEC

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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
Mega-Vit Vitrectomy Infusion Tube and Cutting Heads	**	**	14-386	IIa
Bonn Injection Set, sterile	**	**	15-895	Is*
Single-Use Adapters, sterile	**	**	13-922	Is*
Single-use endoprobes, sterile	**	**	17-809	IIa
Single-Use Light Conductors / Fiber Optics, sterile	**	**	12-345	IIa
Single-Use Irrigation Cannula, sterile	**	**	10-573	Is*
Measuring Instruments	**	**	15-621	Im*

* With Class I products placed on the market in sterile condition and Class I devices with a measuring function application of the above mentioned Annex and the intervention by the notified body is limited to:

- in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions,
- in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

** According to current product list.



Frankfurt am Main, June 13, 2014



Wilfried Baldschief
Certification Body
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