

# EC Certificate - Full Quality Assurance System

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

**No.** CE 711663  
**Issued To:** Geuder AG  
Hertzstraße 4  
69126 Heidelberg  
Germany

In respect of:

**Design, development and manufacture of ophthalmic surgical systems and accessories for surgical procedures in the anterior and posterior eye segments.**

**Auslegung, Entwicklung und Produktion von ophthalmo-chirurgischen Systemen und Zubehör für Operationen in den vorderen und hinteren Augenabschnitten.**

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: **2019-07-29**

Date: **2019-07-29**

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.

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## Supplementary Information to CE 711663

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**Hertzstraße 4**  
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**Germany**

NBOG Code	Device Name	Intended Purpose per IFU
<b>Class IIb</b>		
MD 1105 MDS 7010	Megatron surgical systems (incl. G-28510 foot switch resp. G-28541)	For surgical procedures in the anterior and posterior eye segments in ophthalmological surgery.
MD 1105 MDS 7010	Megatron S4 and Megatron S4 HPS surgical systems (incl. G-30543 foot switch)	For surgical procedures in the anterior and posterior eye segments in ophthalmological surgery.

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