

# EC Certificate

## Full Quality Assurance System MDD Annex II excl. 4

Registration No.: HD 1785176-1

Manufacturer: GEOMED Medizin-Technik  
GmbH & Co. KG  
Ludwigstaler Str. 27  
78532 Tuttlingen  
Germany

Products: Non-active surgical instruments and arm Systems

Products included:

- ASSISTO arm system
- Suction tubes

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3337703-30

Effective date: 2020-12-08

Expiry date: 2024-05-26

Issue date: 2020-12-08



  
Roland Gruber  
TÜV Rheinland LGA Products GmbH  
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	GEOMED Medizin-Technik GmbH & Co. KG Ludwigstaler Str. 27 78532 Tuttlingen Germany	Non-active surgical instruments and arm systems
/02	PT GEOMED INDONESIA Kawasan Industri Candi B10-11 Tahap V Block C6 No. Jl. Gatot Subroto Semarang 50181 Indonesia	Non-active surgical instruments and arm systems

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