

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60141207 0001

Report No.: 21241071 018

Manufacturer: Nouvag AG
St. Gallerstr. 23-25
9403 Goldach
Schweiz

Products: Medical devices
(see attachment for products included)

Replaces Certificate, Registration no.: HD 60108201 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2019-08-30

Date: 2019-08-30

Notified Body

Roland Gruber



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60141207 0001
Report No.: 21241071 018

Manufacturer: Nouvag AG
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included products:

- Motor systems for the oral and maxillofacial surgery, endodontics, facial and skull surgery, plastic surgery, spinal surgery, ENT surgery, orthopedics, traumatology, gynecology, urology and laparoscopy
- Handpieces for the oral and maxillofacial surgery, facial and skull surgery, plastic surgery, spinal surgery, ENT surgery, orthopedics, traumatology, gynecology, urology and laparoscopy
- Suction pumps for the plastic and general surgery, gynecology and obstetrics
- Infiltration pumps for the plastic and general surgery, endodontics, angiology, endoscopy, laparoscopy, gastroenterology, traumatology and orthopedics

Date: 2019-08-30

Notified Body

Roland Gruber



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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
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Registration No.: HD 60141207 0001
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Manufacturer: Nouvag AG
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- rotating instruments for the oral and maxillofacial surgery, facial and skull surgery, plastic surgery, spinal surgery, ENT surgery, orthopedics, traumatology, gynecology, urology and laparoscopy
- Saw blades and rasps for the oral and maxillofacial surgery, facial and skull surgery and orthopedics
- Blades for the oral and maxillofacial surgery, facial and skull surgery, plastic surgery, ENT surgery, traumatology, gynecology, urology and laparoscopy
- Tubing sets for the oral and maxillofacial surgery, facial and skull surgery, plastic and general surgery, angiology, endoscopy, laparoscopy, gynecology and obstetrics, urology, gastroenterology, traumatology and orthopedics

Date: 2019-08-30

Notified Body

Roland Gruber

