TÜVRheinland®

EC Certificate

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

Registration No.: HD 60143493 0001

Report No.: 21220581 021

Manufacturer:
INTERCUS GmbH
Zu den Pfarreichen 5
07422 Bad Blankenburg
Deutschland

Products:
non active orthopedic implants and rotating instruments
(see attachment for products included)

Replaces Certificate, Registration No.: HD 60097198 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: 2019-10-09

Date: 2019-10-09

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60143493 0001
Report No.: 21220581 021

Manufacturer: INTERCUS GmbH
Zu den Pfarreichen 5
07422 Bad Blankenburg
Deutschland

Products included:

- Screws, Bone
- Plates, Bone
- Wires, Bone
- Nail-systems, Bone
- Drill bits

Notified Body

Date: 2019-10-09

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle