

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

TÜVRheinland

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



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.: Report No.:

HD 60143493 0001

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

Date: 2019-10-09

Notified Body

Roland Gruber

TÜVRheinland