EC Certificate

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

Registration No.: HD 60140582 0001

Report No.: 21255151 011

Manufacturer:

Medartis AG
Hochbergerstr. 60E
4057 Basel
Schweiz

Products:

Osteosynthesis, stabilization and splinting of bones and teeth

(see attachment for products included)

Replaces Certificate, Registration No.: HD 60117741 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: 2019-09-11

Date: 2019-09-11

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH Zertifizierstelle

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.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60140582 0001
Report No.: 21255151 011

Manufacturer:
Medartis AG
Hochbergerstr. 60E
4057 Basel
Schweiz

Products included:

Distractors
- MODUS Distraction

Plates, Bone, Mesh, Metallic, Screws, Bone
- MODUS Mandible , MODUS Recon, MODUS Midface, MODUS Cranium

Orthopedic Internal Fixation System
- APTUS Hand, APTUS Wrist, APTUS Elbow, APTUS Shoulder, APTUS Foot, APTUS Cannulated Screws

Wires, Bone
- APTUS Hand, APTUS Wrist, APTUS Elbow, APTUS Shoulder, APTUS Foot, APTUS Cannulated Screws

Prostheses, Joint, Mandible
- MODUS Mandible

Notified Body

Date: 2019-09-11

Roland Gruber

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60140582 0001
Report No.: 21255151 011

Manufacturer:
Medartis AG
Hochbergerstr. 60E
4057 Basel
Schweiz

Products included:

Orthodontic anchor plate
- MODUS Orthodontic

Burs, Oral Surgery
- MODUS Mandible, MODUS Recon, MODUS Midface, MODUS Orthodontic, MODUS Cranium

Burs, Orthopedic
- APTUS Hand, APTUS Wrist, APTUS Elbow, APTUS Shoulder, APTUS Foot, APTUS Cannulated Screws

Splints, Moldable
- MODUS Midface, MODUS Mandible

Notified Body

Date: 2019-09-11

Roland Gruber

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle