TÜVRheinland®

EC Certificate

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

Registration No.: HD 60112578 0001

Report No.: 21252838 001

Manufacturer:

steco-System-Technik
GmbH & Co. KG
Kollaustr. 6
22529 Hamburg
Deutschland

Products:

Design/development and production of attachments
for dental, oral, gnatho and facial medical science

(see attachment for sites included)

Replaces Approval, Registration No.: HD 60040203 0001

Expiry Date: 2021-07-27

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: 2016-07-28

Date: 2016-07-27

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. U. Frenkert

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®

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60112578 0001
Report No.: 21252838 001

Manufacturer: steco-System-Technik GmbH & Co. KG
Kollaustr. 6
22529 Hamburg
Deutschland

Site included:

steco-System-Technik GmbH & Co. KG
Alkenbrede 3
32657 Lemgo
Germany

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2016-07-27

Dipl.-Ing. U. Frenkert