EC Certificate

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

Registration No.: HD 60105631 0001

Report No.: 21238500 001

Manufacturer:
froximun aktiengesellschaft
Neue Str. 2a
38838 Schlanstedt
Deutschland

Products:
Dermal and oral medical devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60041355 0001

Expiry Date: 2020-11-05

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.

Notified Body

Effective Date: 2015-11-06

Date: 2015-11-06

Dr. K. Kluge

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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Doc. 1/1, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60105631 0001
Report No.: 21238500 004

Manufacturer: froximun aktiengesellschaft
Neue Str. 2a
38838 Schlanstedt
Deutschland

Products included:

- TOXAPREVENT MEDI PURE
- TOXAPREVENT MEDI PLUS
- TOXAPREVENT MEDI AKUT
- TOXAPREVENT SKIN
- TOXAPREVENT HALISTOP

Notified Body

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2017-07-12