

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

Registration No.: HD 60121676 0001

Report No.: 21191933 007

Manufacturer: Cavex Holland BV
Fustweg 5
2031 CJ Haarlem
Netherlands

Products: Dental Consumables

(see attachment for products included)

Replaces Certificate, Registration No.: HD 60083644 0001

Expiry Date: 2022-08-04

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: 2017-12-15

Date: 2017-12-15

Notified Body


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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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Products included:

- Dental Amalgam Alloys
 - Cavex Non Gamma 2
 - Cavex Octight
 - Cavex Avalloy
- Dental Cements
 - Cavex Temporary Cement
 - Cavex Glass Ionomer Cement
- Dental Impression Disinfectant
 - Cavex ImpreSafe
- Dental Desensitizer Gel
 - Cavex Bite&White ExSense

Date: 2017-12-15

Notified Body


Dipl.-Ing. U. Frenkert



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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Products included:

- Dental Restorative Materials
 - Quadrant Anterior Shine
 - Quadrant Universal LC
 - Quadrant Flow
 - Quadrant UniBond
 - Quadrant Uni-1-Bond
 - Quadrant Total Etch
 - Quadrant FiniSense
 - Quadrant Uni-SE-Bond

Date: 2017-12-15

Notified Body


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