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Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

DiaDent Group International
16, Osongsaengmyeong 4-ro
Osong-eup
Heungdeok-gu, Cheongju-si
CHUNGCHEONGBUK-DO, 28161
REPUBLIC OF KOREA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date January 15, 2016

Application for : Vollst. QMS, Anhang II MDD
Certificate No. : HD 60102396 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. HD 60102396 0001 replacing the previous certificate.

With issue date of the new certificate, the previous certificate (number see new certificate) has become invalid.

Kind regards

Certification body

M.Sc. M. Aihara

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

EC Certificate

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

Registration No.: HD 60102396 0001

Report No.: 12022722 001

Manufacturer:
DiaDent Group International
16, Osongsaengmyeong 4-ro
Osong-eup
Heungdeok-gu, Cheongju-si
Chungcheongbuk-do, 28161
Republic of Korea

Products:
See attachment for products included

Replaces Approval, Registration NO.: HD 60096170 0001

Expiry Date: 2020-06-01

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: 2016-01-15

Date: 2016-01-15

Notified Body

M.Sc. M. Aihara

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®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60102396 0001
Report No.: 12022722 001

Manufacturer:
DiaDent Group International
16, Osongsaengmyeong 4-ro
Osong-eup
Heungdeok-gu, Cheongju-si
Chungcheongbuk-do, 28161
Republic of Korea

Products:

- Gutta Percha Obturators
- Endodontic Filling Materials
- Bonding Agents
- Pit and Fissure Sealants
- Light-cured Composite Resin
- Light-cured Radiopaque Flowable Composite Resin
- Root Canal Filling Material
- Temporary Filling Material
- Polymer-based Filling Restorative Material
- Root Canal Cleanser
- Etching Agents
- Hydraulic Temporary Restorative Material
- Dual-cured Composite Resin
- Dental Temporary Cement
- Root Canal Sealing Material

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Date: 2016-01-15

M.Sc. M. Aihara

Business Stream Products
Certification Department

TÜVRheinland®
LGA
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TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

DiaDent Group International
16, Osongsaengmyeong 4-ro
Osong-eup
Heungdeok-gu, Cheongju-si
CHUNGCHEONGBUK-DO, 28161
REPUBLIC OF KOREA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date January 15, 2016

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60102395 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60102395 0001 replacing the previous certificate.

With issue date of the new certificate, the previous certificate (number see new certificate) has become invalid.

Kind regards

Certification body

M.Sc. M. Aihara

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

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Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60102395 0001

Report No.: 12022722 001

Manufacturer:

DiaDent Group International
16, Osongsaengmyeong 4-ro
Osong-eup
Heungdeok-gu, Cheongju-si
Chungcheongbuk-do, 28161
Republic of Korea

Products:

Endodontic Files, Sterile Paper Points, Gutta Percha Points, Disposable Sterile Irrigation Probe Needle Tips and Gutta Percha Obturation System

Replaces Approval, Registration No.: DD 60096169 0001

Expiry Date: 2020-06-01

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2016-01-15

Date: 2016-01-15

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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