TÜVRheinland®
LGA
Precisely Right.

Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

CDM Center of Excellence Ltd.
Golden Land Building Office 1302A,
Liangmaqiao Road No.32,
Chaoyang District,
100125 BEIJING
P.R. CHINA

Contact

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

Date February 25, 2020

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60146829 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 60146829 0001
replacing the previous certificate.

Kind regards

Certification body

Wenxiang Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

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Board of Management

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Supervisory Board

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Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

TÜVRheinland®

EC Certificate

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

Registration No.: DD 60146829 0001

Report No.: 16804015 009

Manufacturer:
CDM Center of Excellence Ltd.
Golden Land Building Office 1302A,
Liangmaqiao Road No.32,
Chaoyang District,
100125 Beijing
P.R. China

Products: Medical Devices

(See attachment for Products included)

Replaces Approval, Registration No.: DD 60126887 0001

Expiry Date: 2024-05-26

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: 2020-02-11

Date: 2020-02-11

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Wenxiang Zhang

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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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60146829 0001
Report No.: 16804015 009

Manufacturer:
CDM Center of Excellence Ltd.
Golden Land Building Office 1302A,
Liangmaqiao Road No.32,
Chaoyang District,
100125 Beijing
P.R. China

Products:
- Disposable syringe sets
- Infusion sets
- Disposable needles
- Dental needles for single use
- Dental root-canal instruments
- Sterile absorbent paper points
- Gutta percha points
- Latex surgical gloves
- Diamond dental rotary instruments-sterile
- non-sterile tungsten carbide dental burs
- Medical x-ray films
- Intraradicular posts
- Light-curing dental bonding agents/adhesives
- Light-curing dental pit and fissure sealants
- Light-curing dental composite resins
- Light-curing dental temporary filling materials
- Dental etching agents
- Dental filling materials
- Dental cements
- Light curing cavity liner
- Disposable saliva ejectors
- Disposable aspirator tips

Notified Body

TÜV Rheinland LGA Products GmbH

Date: 2020-02-11

Wenxiang Zhang

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Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60146829 0001
Report No.: 16804015 009

Manufacturer:
CDM Center of Excellence Ltd.
Golden Land Building Office 1302A,
Liangmaqiao Road No.32,
Chaoyang District,
100125 Beijing
P.R. China

Products:
- Disposable dental air water syringe tips
- Alcohol free surface solution and wipes for disinfecting non invasive medical devices
- Materials for the manufacturing of temporary crowns and bridges

Aspects of manufacture concerned with securing and maintaining sterile conditions:
- Sterile irrigation needles for single use
- Latex examination gloves sterile
- Nitrile examination gloves sterile
- PVC gloves sterile
- Sterile non-woven surgical gowns
- Sterile Gauze swab without x-ray detectable
- Sterile Non-woven swab without x-ray detectable
- Sterile Absorbent cotton rolls
- Sterile dental instrument kits

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierung

Date: 2020-02-11

Wenxiang Zhang

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