

Business Stream Products Certification Department

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

JSC « EP «VladMiVa» Studencheskaya str. 19 RUS-308023 BELGOROD Contact

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

Date July 23, 2019

Application for : Vollst. QMS, Anhang II MDD
Certificate No. : HD 60140823 Sheet 0001
Device : Only for QM-System audit

Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate No. HD 60140823 0001.

Kind regards

Certification body

Rafal Byczkowski

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 <u>www.tuv.com/safety</u>

Board of Management

Dipl.-Ing. Jörg Mähler, Spokesman

Dipl.-Kfm. Dr. Jörg Schlösser

Chairman of the Supervisory Board

Dipl.-Ing. Ralf Scheller

Nuremberg HRB 26013 VAT No.: DE 811835490



EC Certificate

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

Registration No.:

HD 60140823 0001

Report No.:

26300428 002

Manufacturer:

JSC «EP«VladMiVa» Studencheskaya str. 19

308023 Belgorod

Russia

Products:

See attachments for scope incuded

Expiry Date:

2024-05-26

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 merked of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date:

2019-07-22

Date:

2019-07-22

Notified Body

Rafal Byczkowski

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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Zifizierungsst

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

Doc. 1/2, Rev.0

Attachment to Certificate

Registration No.:

HD 60140823 0001

Report No.: 26300428 002

Organization:

JSC «EP«VladMiVa» Studencheskaya str. 19 308023 Belgorod

Russia

Scope included:

- Non-sterile restorative dental materials
- Non-sterile dental adhesives
- Non-sterile dental root canal sealing materials
- Non-sterile temporary filling dental materials (cements)

Notified Body

TÜVRheinland

TÜVRheinland

Rafal Byczkowski

Date: 2019-07-22



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev.0

Attachment to Certificate

Registration No.:

HD 60140823 0001

Report No.:

26300428 002

Organization:

JSC «EP«VladMiVa» Studencheskaya str. 19 308023 Belgorod

Russia

Scope included:

- Non-sterile long term filling dental materials (cements)
- Non-sterile temporary filling dental materials
- Non-sterile etching gels

Notified Body

TÜVRheinland

TÜVRheinland

Rafal Byczkowski

Date: 2019-07-22