

## **EC** Certificate Directive 93/42/EEC Annex V **Production Quality Assurance** Medical Devices

Registration No.: DD 60146058 0001

Report No.:

50224950 002

Manufacturer:

CAI YU DENTAL MATERIALS CO.,LTD

No.35, standardization workshop of hua

county industrial gathering area, Hua county,

456400 Henan

P.R. China

Products:

Synthetic Resin Teeth

**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:

2020-01-20

Date:

2020-01-20

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.

Notified Body



## **Business Stream Products Certification Department**

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

CAI YU DENTAL MATERIALS CO.,LTD county industrial gathering area,Hu 456400 HENAN P.R. CHINA

Contact

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

Date January 20, 2020

Application for : QMS Produktion, Anhang V MDD

Certificate No. : DD 60146058 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. DD 60146058 0001.

Kind regards

Certification body

Jing Zhang

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

**Board of Management** 

Jörg Mähler, Spokesman

Dipl.-Kfm. Dr. Jörg Schlösser

Chairman of the Supervisory Board

Dipl.-Ing. Ralf Scheller

Nuremberg HRB 26013 VAT No.: DE 811835490