

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

Registration No.: DD 60145841 0001

Report No.: 50305865 002

Manufacturer: Audental Bio-Material Co., Ltd.
2-2, 88 Jingche Road, Songjiang District
201611 Shanghai
P.R. China

Products:
-Dental Alloys
-Dental Zirconia Ceramics

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: * 2020-01-21

Date: 2020-01-21

Notified Body



Jing 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.

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2011508-1

Organization: Audental Bio-Material Co., Ltd.
2-2, 88 Jingche Road,
Songjiang District,
201611 Shanghai
P.R. China

Scope: Manufacture and Distribution of Dental Alloys and Dental Zirconia Ceramics

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190143689-110
Effective date: 2023-03-14
Expiry date: 2025-12-27
Issue date: 2023-03-14




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