EC Certificate

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

TÜVRheinland®

Registration No.: HD 60108834 0001

Report No.: 15065176 003

Manufacturer:

Jiangsu Trausim Medical
Instrument Co., Ltd.
No. 18 Jincheng Road
Wujin Economic Development Zone
Changzhou
213149 Jiangsu
China

Products: Dental Implant Systems, Dental Drills

Replaces Approval, Registration no.: HD 60091142 0001

Expiry Date: 2019-02-04

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: 2016-09-07

Date: 2016-09-07

Notified Body

TÜV Rheinland LGA Products GmbH

X. Ren

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.