EC Certificate

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

Registration No.: HD 60144744 0001

Report No.: 16803723 011

Manufacturer:

Beijing YHJ Science and Trade
Co., Ltd.
Room 6023, 6th Floor, No.101, South Road
West 4th Ring Road, Fengtai District
Fengtai District
100070 Beijing
China

Products:

- Hydroxyapatite Orbital Sphere Implant
- Hydroxyapatite Synthetic Bone Graft

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60139558 0001

Expiry Date: 2024-05-27

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: 2019-12-06

Date: 2019-12-06

Notified Body

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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Doc 1/1, Rev 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60144744 0001
Report No.: 16803723 011

Manufacturer:
Beijing YHJ Science and Trade Co., Ltd.
Room 6023, 6th Floor, No.101, South Road West 4th Ring Road, Fengtai District
Fengtai District
100070 Beijing
China

Sites included:

South of Qintun Village,Xingshou Town,
Changping District, Beijing 102212, China

Rm612, No.1 Building, GuoYingYuan, NanXiaoJie,
XiZhiMen Xicheng District, Beijing 100035, China

Notified Body

Date: 2019-12-06

Wenxiang Zhang