



TÜVRheinland®

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

Registration No.: HD 60126883 0001

Report No.: 16803723 004

Manufacturer: Beijing YHJ Science and Trade
Co., Ltd.
Room A202, Painoly Culture
Creative Industry Park
No. 40 Central South 4th Ring Road
Fengtai District
100075 Beijing
China

Products:
- Hydroxyapatite Orbital Sphere Implant
- Hydroxyapatite Synthetic Bone Graft

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60099312 0001

Expiry Date: 2020-03-23

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: 2018-05-25

Date: 2018-05-25

Notified Body



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

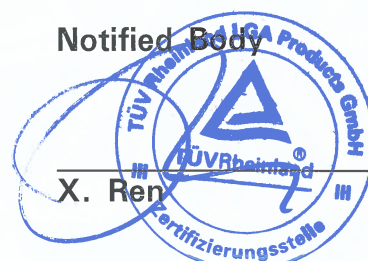
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No. 40 Central South 4th Ring Road
Fengtai District
100075 Beijing
China

Sites included:

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

Date: 2018-05-25



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Beijing YHJ Science and Trade
Co., Ltd.**
**Room A202, Painoly Culture
Creative Industry Park
No. 40 Central South 4th Ring Road
Fengtai District
100075 Beijing
China**

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
Hydroxyapatite Orbital Sphere Implant and
Hydroxyapatite Synthetic Bone Graft
(see attachment for additional sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-05-25
Certificate Registration No.: SX 60126884 0001
An audit was performed. Report No.: 16803723 004
This Certificate is valid until: 2021-03-23

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-05-25



X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60126884 0001
Report No.: 16803723 004

Organization: Beijing YHJ Science and Trade
Co., Ltd.
Room A202, Painoly Culture
Creative Industry Park
No. 40 Central South 4th Ring Road
Fengtai District
100075 Beijing
China

Scope:

Sites included:

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

Design and Development, Manufacture of
Hydroxyapatite Orbital Sphere Implant and
Hydroxyapatite Synthetic Bone Graft

Rm 612, No.1 Building, GuoYingYuan, NanXiaoJie, XiZhiMen,
Xicheng District, Beijing, 100035, China

Distribution of Hydroxyapatite Orbital Sphere Implant and
Hydroxyapatite Synthetic Bone Graft

Certification Body



Date: 2018-05-25

