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Date: 2021.02.02 12:58:34 EET
Reason: MoldSign Signature
Location: Moldova

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System

No. 11 0673 QS/NB

The quality system of manufacturer

Samay Surgical

Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval (Shapar) – 360 024, Dist. Rajkot, Gujarat, India

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Orthopaedic Implants, Spinal Implants

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. 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.

Valid from: 2016-08-09
Valid until: 2021-08-08
First Issued: 2011-08-09
Revision: b

Date: 2016-08-09

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

EC Certificate

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

Registration No.: HD 60107628 0001

Report No.: 15087301 001

Manufacturer:
Jiangsu Ideal Medical Science & Technology Co., Ltd.
East Area,Jinfeng Industry Park
Zhangjiagang City
215625 Jiangsu
China

Products: Medical Devices

(see attachment for products included)

Expiry Date: 2023-02-17

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.

Notified Body

Effective Date: 2020-02-22

Date: 2020-02-22

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60107628 0001
Report No.: 15087301 001

Manufacturer:
Jiangsu Ideal Medical Science & Technology Co., Ltd.
East Area,Jinfeng Industry Park
Zhangjiagang City
215625 Jiangsu
China

Products:

- Anatomic Type Metallic Locking Bone Plates & Screw Systems
- Metallic Bone Plate & Screw Systems
- Spinal Fixation Devices
- Metallic Bone Pins
- Cannulated Bone Screws
- Metallic Interlocking Intramedullary Nails
- Centrum Fusion Devices
- Binding Wires
- Titanium Meshes

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

X. Ren

Date: 2020-02-22

| evaluate | assess | certify |

assessors of quality

Management System Certificate

Certificate No. **MD-QMS/91/R/1933**

This is to certify that

Samay Surgicals

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, Nh-8b,
Veraval (Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

has been found to conform to the requirements of
Medical Devices - Quality Management System Standard :

ISO 13485:2016

This certificate is valid for the following scope :

**Design, Manufacture & Supply of Orthopedic Implants,
Spinal Implant & related Instruments.**

Initial Certification	:	20th August, 2011
Re-certification	:	20th August, 2017
Valid until	:	19th August, **2022**

Authorised Signatory

This Certificate is valid when confirmed by data listed in the International Register of Quality Assessed Organisations <www.irqao.org>.
Further clarification regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the certified organization.
Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid.

Zenith Quality Assessors Pvt. Ltd.
(Management System Certification Division, MSCD002)
306, 4th Floor, Sai Apex, Near Datta Mandir, Viman Nagar, Pune - 411 014, Maharashtra, India.
www.zenith-worldwide.com

Accreditation Body : ACCREDITATION SERVICE FOR CERTIFYING BODIES (EUROPE) Ltd.
6, Ferris Place, Bournemouth, Dorset, BH8 0AU, United Kingdom.
www.ascb.co.uk

C/ASCB/MDQMS16/00/121216 (Cl.8.2)

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Jiangsu Ideal Medical Science & Technology Co., Ltd.
East Area,Jinfeng Industry Park
Zhangjiagang City
215625 Jiangsu
China

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

Design and Development, Manufacture and Distribution of Medical Devices (see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date:	2020-02-22
Certificate Registration No.:	SX 60107629 0001
An audit was performed. Report No.:	15087301
001 This Certificate is valid until:	2023-02-17

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-02-22

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle
X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60107629 0001
Report No.: 15087301 001

Organization:
Jiangsu Ideal Medical Science & Technology Co., Ltd.
East Area,Jinfeng Industry Park
Zhangjiagang City
215625 Jiangsu
China

Scope:

Products:

- Anatomic Type Metallic Locking Bone Plates & Screw Systems
- Metallic Bone Plate & Screw Systems
- Spinal Fixation Devices
- Metallic Bone Pins
- Cannulated Bone Screws
- Metallic Interlocking Intramedullary Nails
- Centrum Fusion Devices
- Binding Wires
- Titanium Meshes

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-02-22

X Ren