

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

Registration No.: DD 60143915 0001

Report No.: 50259256 002

Manufacturer:

XinXiang Xinda Technology

Co.,Ltd

Zhangsanzhai Industrial Zone, Changyuan County, Xinxiang City

453400 Henan Province

China

Products:

Aspects of Manufacture concerned with Securing and

Maintaining Sterile Conditions:

Surgical Scrub Brushes, Applicator Brushes

Expiry Date:

2024-05-27

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:

2019-12-17

Date:

2019-12-17

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

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

XinXiang Xinda Technology Co. Ltd Zhangsanzhai Industrial Zone, Changyuan County, Xinxiang City 453400 Henan Province

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

> Manufacture and Distributions of Surgical Scrub Brushes and Applicator Brushes

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:

2019-12-17

Certificate Registration No.:

SX 60143916 0001

An audit was performed. Report No.: 50259256 002

This Certificate is valid until:

2022-09-18

Certification Body

Akkreditierungsstelle D-ZM-14169-01-02

Date 2019-12-17

Jing Zhang

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