

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

Registration No.: HD 60112688 0001

Report No.: 15096014 001

Manufacturer: Shanghai SA Medical & Plastic
Instruments Co., Ltd.
No. 18, Hengxi Road
Pujiang Industrial Zone
Minhang District
Shanghai 201114
China

Products: Spinal Needles, Epidural Needles, Nerve Block
Needles, Bone Marrow Needles, Introducer Needles

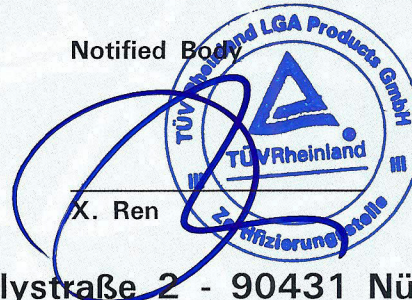
Replaces Approval, Registration No.: HD 60087230 0001

Expiry Date: 2021-08-14

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: 2016-08-15

Date: 2016-08-08



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

**Shanghai SA Medical & Plastic
Instruments Co., Ltd.
No. 18, Hengxi Road
Pujiang Industrial Zone
Minhang District
Shanghai 201114
China**

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

**Design and Development, Manufacture and Distribution of
Needles for Medical Use**

(This certificate information can be searched on CNCA
official website <http://www.cnca.gov.cn>)

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

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

Effective Date: 2016-08-08
Certificate Registration No.: SY 60112690 0001
An audit was performed. Report No.: 15096015 001
This Certificate is valid until: 2018-09-14

Date 2016-08-08

Certification Body



X. Ren

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