

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

Registration No.: DD 60144042 0001

Report No.: 15094396 007

Manufacturer: Shanghai Mekon Medical
Devices Co., Ltd.
526, No. 697-3 Lingshi Road
200072 Shanghai
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60124131 0001

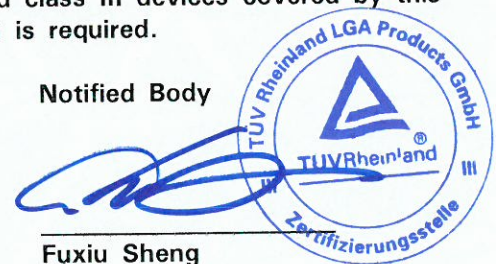
Expiry Date: 2024-05-26

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: 2021-01-30

Date: 2021-01-30

Notified Body



Fuxiu Sheng

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

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60144042 0001
Report No.: 15094396 007

Manufacturer: Shanghai Mekon Medical
Devices Co., Ltd.
526, No. 697-3 Lingshi Road
200072 Shanghai
P.R. China

Products:

Infusion Sets, Disposable Needles, Scalp Vein Sets, Dental
Needles for Single Use, Blood-Collecting Needles, Disposable
Insulin Pen Needles, Syringes, Transfusion Sets,
Burette-Type Infusion Sets, Fistula Needles, Syringes
for Insulin, Sterile I.V. Catheter for Single Use, Huber
Needles, Biopsy Needles, Safety Needles,
Self-destruction Safety Syringes, Safety Scalp Vein Sets,
Safety Blood-collecting Needles, Safety Insulin Needles for
Single Use, Extension Sets, Sterile Irrigation Needles for
Single Use;

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

Sterile Infusion Connector and Accessory for Single Use,
Stopcocks for Single Use, Urinal Bags, Blunt Filter Needles
for Single Use

Date: 2021-01-30

Notified Body



Fuxiu Sheng