

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

Registration No.: DD 60131859 0001

Report No.: 15085898 004

Manufacturer: Hubei Kangning Protective

Products Co., Ltd.

Special No.1 Xuefu Road 433000 Xiantao City, Hubei

China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No: DD 60104371 0001

Expiry Date: 2023-10-22

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: 2018-12-04

Date: 2018-12-04

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.



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

DD 60131859 0001

Report No .: 15085898 004

Manufacturer:

Hubei Kangning Protective

Products Co., Ltd. Special No.1 Xuefu Road 433000 Xiantao City, Hubei

China

Aspects of manufacture concerned with securing and maintaining sterile conditions of Medical Non-woven Masks, Medical Non-woven Gowns, Medical Coveralls

Site included:

Jiandi Village, Huchang Town, Xiantao City, Hubei, China

Date: 2018-12-04

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