

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

Registration No.: DD 60098446 0001

Report No.: 15072381 001

Manufacturer: Wuhan Huaxin Non-woven
Co., Ltd.
2# Wanling Village, Yong'an Street
Caidian Area
Wuhan
430013 Hubei
China

Products: Aspects of manufacture concerned with securing and
maintaining sterile conditions: Face Masks, Surgical Gowns,
Non-woven Coveralls, Surgical Drapes

Expiry Date: 2019-10-24

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: 2015-03-03

Date: 2015-03-03



Notified Body

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.