EC Certificate

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

Registration No.: DD 60139107 0001

Report No.: 15065841 009

Manufacturer:

Xiantao Zhongtai Protective
Products Co., Ltd.
3#, Taizi Lake Industry Park
Pengchang Town, Xiantao City
433018 Hubei Province
P.R. China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions of Face Masks, Surgical Gowns, Surgical Caps, Surgical Drapes, Surgical Drape Packs

Replaces Approval, Registration No.: DD 60091096 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: 2020-01-23

Date: 2020-01-23

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.