

**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



**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.