

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

**Registration No.:** DD 60135422 0001

**Report No.:** 15083140 006

**Manufacturer:** Xiantao Tongda Non-woven  
Products Co., Ltd.  
No. 28, Pengchang Road  
433018 Xiantao  
China

**Products:** Aspects of manufacture concerned with securing and  
maintaining sterile conditions:  
Face Masks, Surgical Gowns, Coveralls, Caps  
Replaces Approval, Registration No.: DD 60102531 0001

**Expiry Date:** 2024-01-16

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:** 2019-07-16

**Date:** 2019-07-16



Notified Body

M.Sc. M. Aihara

**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.



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Xiantao Tongda Non-woven  
Products Co., Ltd.**  
No. 28, Pengchang Road  
433018 Xiantao  
China

has established and applies a quality management system for medical devices  
for the following scope:

**Manufacture and Distribution of Face Masks,  
Surgical Gowns, Coveralls and Caps**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-07-16  
Certificate Registration No.: SX 60135423 0001  
An audit was performed. Report No.: 15083140 006  
This Certificate is valid until: 2022-01-16

Certification Body



Date 2019-07-16



*M. Sc. M. Aihara*  
M.Sc. M. Aihara

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