

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

**Registration No.:** DD 60111758 0001

**Report No.:** 15095978 001

**Manufacturer:** Sunsmed Protective Products Ltd.  
No. 18, Industrial Park, Maozui Town  
Xiantao City  
433000 Hubei  
China

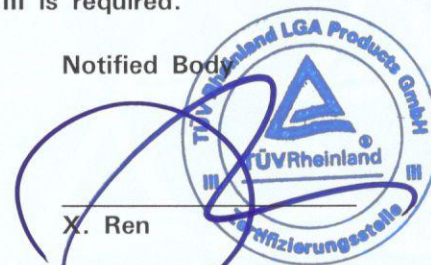
**Products:** Aspects of manufacture concerned with securing and maintaining sterile conditions:  
Sterile Surgical Caps, Sterile Surgical Face Masks,  
Sterile Surgical Gowns, Sterile Bed Protections,  
Sterile Surgical Drapes, Sterile Surgical Packs

**Expiry Date:** 2021-08-11

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:** 2016-08-12

**Date:** 2016-08-12



**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

**Sunsméd Protective Products Ltd.**  
**No. 18, Industrial Park, Maozui Town**  
**Xiantao City**  
**433000 Hubei**  
**China**

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

**Manufacture and Distribution of Medical Devices**  
**(see attachment for products included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012**  
**EN ISO 13485:2012/AC:2012**

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

Effective Date: 2016-08-12  
Certificate Registration No.: SX 60111759 0001  
An audit was performed. Report No.: 15095978 001  
This Certificate is valid until: 2019-08-11

Certification Body



Date 2016-08-12



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60111759 0001  
**Report No.:** 15095978 001

**Organization:** Sunsmed Protective Products Ltd.  
No. 18, Industrial Park, Maozui Town  
Xiantao City  
433000 Hubei  
China

**Scope:**

**Products:**

- Surgical Caps
- Non Woven Face Masks
- Surgical Gowns
- Isolation Gowns
- Coveralls
- Sleeve Protectors
- Shoe Covers
- Bed Protections
- PE Plastic Aprons
- Surgical Drapes
- Surgical Packs

**Certification Body**



**Date:** 2016-08-12