



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

**Registration No.:** DD 60098979 0001

**Report No.:** 15077288 001

**Manufacturer:** Wuxi Kangyou Medical Products  
Co., Ltd.  
No.168, Chunxiang Industrial Park  
Economic Development Zone  
of Xishan District  
Wuxi  
214101 Jiangsu  
China

**Products:** Alcohol Swabs/Pads



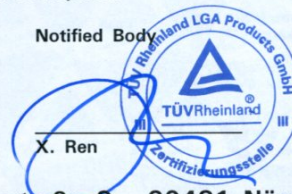
**Expiry Date:** 2020-02-26

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:** 2015-02-27

**Date:** 2015-02-27

Notified Body



**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

**Wuxi Kangyou Medical Products  
Co., Ltd.**  
**No.168, Chunxiang Industrial Park  
Economic Development Zone  
of Xishan District  
Wuxi  
214101 Jiangsu  
China**

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

**Manufacture and Distribution of Alcohol Swabs/Pads**

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: 2015-02-27  
Certificate Registration No.: SX 60098980 0001  
An audit was performed. Report No.: 15077288 001  
This Certificate is valid until: 2018-02-26

Certification Body



Date 2015-02-27



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