

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1532933**

Certificate Holder:

**Lights Medical Manufacture Co., Ltd.**

Unified Social Credit Code: 911202227257222623

Registration Address: No. 19, Quanda Road,  
Wuqing Development Area, Tianjin New Technology Industrial  
Park, 301700 Tianjin, P. R. China

Operation Address: No. 19, Quanda Road,  
Wuqing Development Area, 301700 Tianjin, P. R. China

Scope:

Manufacture and Distribution of Wet Pack Products for Cleaning  
of Medical Devices and Disinfectant Solution

Proof has been furnished by means of an audit that the  
requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2021-04-25 until 2024-04-24.  
It remains valid subject to satisfactory surveillance audits.  
First certification 2015

This certificate information can be searched on CNCA official  
website <http://www.cnca.gov.cn>

2021-04-15

TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln



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

**Registration No.:** DD 60153957 0001

**Report No.:** 16801929 013

**Manufacturer:** Lights Medical Manufacture Co.,Ltd.  
No. 19, Quanda Road,  
Wuqing Development Area  
Tianjin, 301700  
P.R. China

**Products:** Wet Pack Products  
  
Replaces Approval, Registration No.: DD 60143690 0001

**Expiry Date:** 2023-04-17

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:** 2021-04-01

**Date:** 2021-04-01



**Notified Body**

  
Wenxiang 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.



# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 2094470-1

Organization: Lights Medical Manufacture Co., Ltd.  
No.19, Quanda Road, Wuqing Development Area,  
301700 Tianjin, P.R. China

Scope: Manufacture and Distribution of Wet Pack Products

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190131313 110  
Effective date: 2021-04-18  
Expiry date: 2024-04-17  
Issue date: 2021-04-15



A circular purple stamp of TÜV Rheinland LGA Products GmbH with a signature across it. Below the stamp, the text "Wenxiang Zhang" is written, followed by "TÜV Rheinland LGA Products GmbH" and "Tillystraße 2 · 90431 Nürnberg · Germany".  
Wenxiang Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany