

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: same as above

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 2024-04-25 until 2027-04-24.
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>**

2024-01-31



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Authorized responsible office: TÜV Rheinland China Ltd., Room 301, 3F and Room 1203,
12F, Building 4, No.15, Ronghua South Road, Beijing Economic-Technological
Development Area, Beijing (Yizhuang group in high-end industrial area of Beijing Pilot Free
Trade Zone), 100176, P. R. China

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2094470-1
Certificate Holder: Lights Medical Manufacture Co., Ltd.
No.19, Quanda Road,
Wuqing Development Area
301700 Tianjin
P.R. China
Scope: Design and Development, 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.: 190152919-110
Effective date: 2024-04-18
Expiry date: 2027-04-17
Issue date: 2024-03-29
Replaces certificate SX 2094470-1 issued 2024-03-20

This certificate can be validated on <https://www.certipedia.com>


Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2094470-1

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

EUDAMED Single
Registration No.: CN-MF-000023132

Products: Products of class IIa
D0702 - ISOPROPYL ALCOHOL FOR THE DISINFECTION
OF MEDICAL DEVICES

Authorized representative(s): Wellkang Ltd
Enterprise Hub, NW Business Complex, 1 Beraghmore Rd.
Derry, BT48 8SE, Northern Ireland

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-09-29

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 190143821-120

Effective date: 2024-09-29

Expiry date: 2029-09-28

Issue date: 2024-09-29



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This certificate can be validated on <https://www.certipedia.com>

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.



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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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BS-MDR-091

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