

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
10000322642-PA-NA-CHN

Project No.:  
PRJC-597653-2019-PRC-CHN

Valid Until:  
27 May 2024

This is to certify that the quality system of:

### Xuzhou Yongkang Electronic Science Technology Co., Ltd.

4F Building C8, 40 Jingshan Road, Economic and Technological Development Zone,  
Xuzhou, China

For design, production and final product inspection/testing of:  
**UV RADIATION TREATMENT SYSTEM**

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN  
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE  
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:  
**Høvik, 29 October 2020**

For:  
**DNV GL PRESAFE AS**

**Notified Body No.: 2460**

*Sholeh Gheissar*

**Sholeh Gheissar**

The certificate is digitally verified by blockchain  
technology. For more info, see  
[www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.  
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway. Registered Enterprise No: NO 997 067 401 MVA.

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**Jurisdiction**

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	29-10-2020

Products covered by this Certificate:

Product Description	Product Name	Class
UV Radiation Treatment System	YK-6000B, YK-6000B-T, YK-6000D, YK-6000D-T	IIa

The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**

Site Name	Address
Xuzhou Yongkang Electronic Science Technology Co., Ltd.	4F Building C8, 40 Jingshan Road, Economic and Technological Development Zone, Xuzhou, China

**EU Representative**

Llins Service & Consulting GmbH  
Obere Seegasse 34/2, 69124, Heidelberg, Germany



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## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

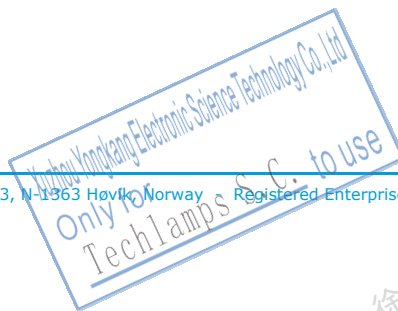
The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate



# APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:  
10000322642-PA-NA-CHN Rev. 0.0

Valid Until:  
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:  
**Xuzhou Yongkang Electronic Science Technology Co., Ltd.**

originally issued in compliance with:  
**the Council Directive 93/42/EEC on Medical Devices, as amended**

Based on assessment and audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A site has been relocated.

Sites covered by certificate (replaces information on certificate)

Site Name	Site Address
Xuzhou Yongkang Electronic Science Technology Co., Ltd.	1st&2nd Floor, 6#01, 6#02, No.6 Building, 1st Phase Economic Development Manufacturing Zone, LIANDO U Valley, No.6 Leye Road, Xuzhou ETDZ, 221000 Xuzhou, PEOPLE'S REPUBLIC OF CHINA

Place and date:  
Høvik, 19 April 2023



For the issuing office:  
DNV Product Assurance AS - Notified Body  
2460  
Veritasveien 1, 1363 Høvik, Norway



Hazem Tinawi  
Technical Reviewer



Appendix to Certificate no.: 10000322642-PA-NA-CHN Rev. 0.0  
Place and date: Høvik, 19 April 2023

<b>Appendix History -</b>		
<b>Revision</b>	<b>Description</b>	<b>Issued Date</b>
0.0	Admin change for removal of Norwegian Accreditation	23 December 2021
1.0	Address changed	19 April 2023

