



**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60126928 0001

**Report No.:** 28417115 002

**Manufacturer:** E-SWIN SAS  
5 Rue de la Noue  
78113 Adainville  
France

**Products:** Medical devices utilizing intense pulsed light technology  
(see attachments for scope and site included)

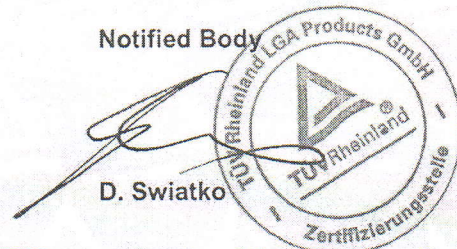
**Expiry Date:** 2023-01-12

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2018-02-05

**Date:** 2018-02-05

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.





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

Doc. 1/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HD 60126928 0001  
**Report No.:** 28417115 002


**Manufacturer:** E-SWIN SAS  
5 Rue de la Noue  
78113 Adainville  
France

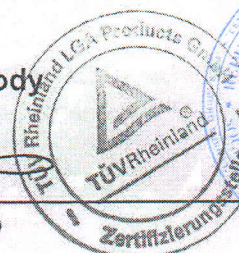
**Scope included:**

- Medical devices utilizing intense pulsed light technology for decrease of unwanted effects connected to the post-surgical scar process
- Medical devices utilizing intense pulsed light technology for treatment of flat, mild pigmented cutaneous lesions
- Medical devices utilizing intense pulsed light technology for hair removal in relation to hormonal or idiopathic hirsutism
- Medical devices utilizing intense pulsed light technology for the treatment of hormonal or inflammatory acne
- Medical devices utilizing intense pulsed light technology for treatment of Meibomian Blepharitis

**Date: 2018-02-05**

**Notified Body**

  
**D. Swiatko**



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

**Attachment to  
Certificate**

**Registration No.:** HD 60126928 0001  
**Report No.:** 28417115 002

**Manufacturer:** E-SWIN SAS  
5 Rue de la Noue  
78113 Adainville  
France

**Site included:**

E-SWIN SAS  
ZA de la Prévôté, rue des Côtes d#Orval  
78550 Houdan  
France

**Activity:** Manufacture

**Date:** 2018-02-05

**Notified Body**



**D. Swiatko**



TÜV Rheinland  
Zertifizierungsstelle





# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**E-SWIN SAS**  
**5 Rue de la Noue**  
**78113 Adainville**  
**France**

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

**Design and development, manufacture, distribution  
and servicing of medical devices utilizing intense pulsed  
light technology (IPL) for therapeutically purposes  
(see attachment for site included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

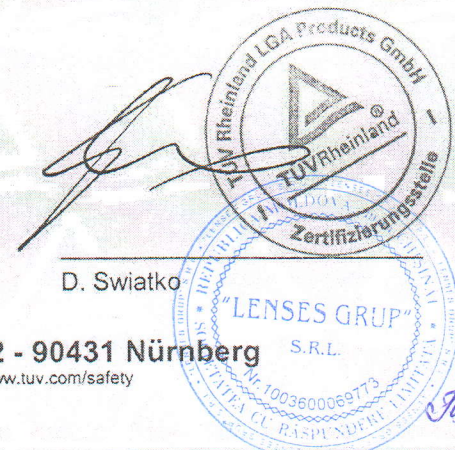
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-02-05  
Certificate Registration No.: SX 60126929 0001  
An audit was performed. Report No.: 28417115 002  
This Certificate is valid until: 2021-01-12

Certification Body



Date 2018-02-05



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

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

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60126929 0001  
**Report No.:** 28417115 002

**Organization:** E-SWIN SAS  
5 Rue de la Noue  
78113 Adainville  
France

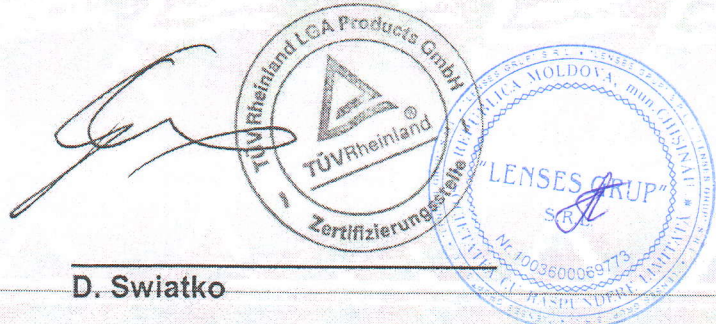
**Scope:**

**Site included:**

E-SWIN SAS  
ZA de la Prévôté, rue des Côtes d#Orval  
78550 Houdan  
France

**Activity:** Manufacturing, distribution and servicing of  
medical devices utilizing intense pulsed light  
technology (IPL) for therapeutically purposes

**Certification Body**



**Date: 2018-02-05**

**D. Swiatko**