TÜVRheinland®

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.

Notified Body

Effective Date: 2018-02-05

Date: 2018-02-05

D. Swiatko

TÜV Rheinland LGA Products GmbH, TÜVRheinland, Zertifizierungsstelle

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.

"LENSES GRUP" Nr. 1003600069773

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TÜVRheinland®

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

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

Notified Body

D. Swiatko

Date: 2018-02-05

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

"LENSES GRUP" S.R.L. Nr. 1003600069773

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Doc. 2/2, Rev. 0

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

Notified Body

D. Swiatko

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierumpsstelle

"LENSES GRUP" S.R.L. Nr. 1003600069775

Date: 2018-02-05

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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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date 2018-02-05

D. Swiatko

"LENSES GRUP" S.R.L.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

"LENSES GRUP" S.R.L. Nr. 1003600069773

Date: 2018-02-05

D. Swiatko