EUROFEEDBACK

ATTESTATION FABRICANT

Nous, soussignés, **Jean-Yves MARTIN**, Président de la société **EUROFEEDBACK**,et **Muriel CHEPY**, Responsable Qualité, attestons que :

- **EUROFEEDBACK** est certifiée EN ISO 13485 : 2016 pour ses activités de Conception, développement, fabrication, vente et prestations associées de dispositifs médicaux à lumière pulsée depuis le 07 février 2011.

- Les dispositifs médicaux à lumière intense pulsée d'**EUROFEEDBACK** respectent la Directive 93/42/EEC depuis le 07 février 2011.


Certificate FR11/00243

SGS

EUROFEEDBACK SAS

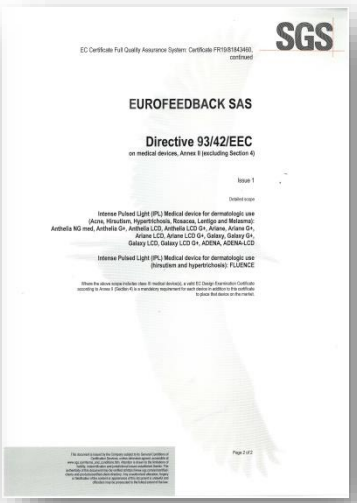
ISO 13485:2016
EN ISO 13485:2016


SGS

EUROFEEDBACK SAS

Directive 93/42/EEC

SGS Belgium NV, Notified Body 1639


SGS

EUROFEEDBACK SAS

Directive 93/42/EEC

EUROFEEDBACK continue à tout mettre en œuvre pour se conformer au règlement européen 2017/745/UE dans les délais de transition définis par la commission européenne.

Jean-Yves MARTIN
Président

Le 18 Juillet 2023

Muriel CHEPY
Responsable Qualité, PCVRR

EC Certificate Full Quality Assurance System: Certificate FR19/81843460

The management system of

EUROFEEDBACK SAS

ZI de la Petite Montagne Sud, 3, rue de l'Aubrac, 91017 EVRY, France

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 24 April 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 07 February 2011
and first certified by SGS Belgium NV since 24 April 2020

Certification is based on reports numbered FR/MD 216647

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

EUROFEEDBACK SAS

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

Intense Pulsed Light (IPL) Medical device for dermatologic use (Acne, Hirsutism, Hypertrichosis, Rosacea, Lentigo and Melasma): Anthelia NG med, Anthelia G+, Anthelia LCD, Anthelia LCD G+, Ariane, Ariane G+, Ariane LCD, Ariane LCD G+, Galaxy, Galaxy G+, Galaxy LCD, Galaxy LCD G+, ADENA, ADENA-LCD

Intense Pulsed Light (IPL) Medical device for dermatologic use (hirsutism and hypertrichosis): FLUENCE

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Certificate FR11/00243

The management system of

EUROFEEDBACK SAS

ZI de la Petite Montagne Sud, 3, rue de l'Aubrac, 91017 EVRY, France

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities
Design, development, manufacture, sales and servicing of Intense Pulsed Light medical devices for dermatologic use.

Conception, développement, fabrication, vente et prestations associées de dispositifs médicaux à lumière pulsée à usage dermatologique.

This certificate is valid from 17 May 2022 until 06 February 2026 and remains valid subject to satisfactory surveillance audits.

Issue 9. Certified since 07 February 2011

Last certificate expiry date 06 February 2023
Recertification audit date 23 November 2022

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

UKAS MANAGEMENT SYSTEMS 0005