EC Certificate Full Quality Assurance System: FR11/00245

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 02 September 2017 until 06 February 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 07 January 2020
Issue 12. Certified since 07 February 2011

Certification is based on reports numbered FR/MD 216647

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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EUROFEEDBACK SAS

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 12

Detailed scope

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

Anthélia NG med. / Anthélia G+

Anthélia LCD / Anthélia 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