EC Certificate Full Quality Assurance System: Certificate US21/819944231

The management system of

Edge Systems LLC

3600 E. Burnett Street,
Long Beach, CA, 90815, United States

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 09 February 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 09 February 2021

Certification is based on reports numbered WW/MC 616821

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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Edge Systems LLC

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

HydraFacial MD Elite®, HydraFacial MD Tower® Dermal abrasion devices for treatment of mild to moderate acne and superficial acne scarring

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.

Additional facilities

2277 Redondo Avenue, Signal Hill, CA, 90755, United States