EC Certificate Full Quality Assurance System: US16/81826456.01

The management system of

Lacey Manufacturing Company LLC

1146 Barnum Avenue,
Bridgeport, CT, 06610, 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 04 October 2017 until 23 August 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 30 June 2017
Issue 2. Certified since 23 August 2016

Certification is based on reports numbered WW/MW 605496

Multiple certificates have been issued for this scope
The main certificate is numbered US16/81826456.00

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 02 0315 M2

Lacey Manufacturing Company LLC

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 2

Detailed scope

Sterile scalpel, sterile monopolar electrocautery pencil, sterile bipolar forceps.

Sterile Pedicle Access Devices.

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

1105 Barnum Ave, Bridgeport, CT 06610, United States