EC Certificate Full Quality Assurance System: Certificate US19/819943483

The management system of

Boston EndoSurgical Technologies, a division 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 13 February 2020 until 23 August 2022
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 23 August 2016
and first certified by SGS Belgium NV since 16 December 2019.

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

Certification is based on reports numbered WW/MW 605496

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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Boston EndoSurgical Technologies, a division of Lacey Manufacturing Company LLC

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Sterile Scalpel, Sterile Electrocautery Pencil, Sterile Bipolar Forceps, Sterile Pedicle Access Needle PAK, Sterile Pedicle Access Needle XPAK, Sterile Access Needle PAK NIM, Sterile Access Needle XPAK NIM, Sterile Access Needle NAV, Sterile Pedicle Access Needle NIM NAV, Sterile Pedicle Access Needle Probes

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