

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Boston Endo-Surgical Technologies, LLC, a division of Lacey Manufacturing Company, LLC

(FIN F000757)

Main Site: 1146 Barnum Avenue, Bridgeport, Connecticut, 06610, United States

Additional site: 1105 Barnum Avenue, Bridgeport, Connecticut, 06610, United States

has been registered by Intertek, an MDSAP recognised auditing organisation, as conforming to the requirements of:

## ISO 13485:2016

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

**Brazil:** Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

**Canada:** Medical Devices Regulations – Part 1- SOR 98/282

**United States:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

### The management system is applicable to:

Design and manufacture of sterile and non-sterile, active and non-active medical devices and components for general surgical, spinal, and orthopaedic applications.

Additional site: Manufacturing

**Certificate Number:**

00077381-03

**Initial Certification Date:**

2018-06-27

**Date of Certification Decision:**

2021-07-01

**Certification Effective Date:**

2021-07-01

**Certification Expiry Date:**

2024-06-26



intertek

A handwritten signature in black ink, appearing to read "Calin Moldovean", written over a horizontal line.

**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA, Inc.  
900 Chelmsford Street  
Lowell, MA, USA 01851

