Certificate US20/819943771

The quality management system of

SGS

ACE Surgical Supply Co., Inc.

1034 Pearl Street, Brockton, MA, 02301, United States Of America

Facility number: F002986

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Canada: Medical Device Regulations SOR/98-282, Part 1

Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68 USA: 21 CFR Part 803 - Medical Device Reporting, 21 CFR Part 806 - Reports of Corrections and Removals, 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design and Manufacture of Sterile Dental Implant System, Implant System Instruments, Sterile Absorbable and Nonabsorbable Sutures, Scalpel Blades, Sterile Bone Screw System, Sterile Extension Tubes, Suction Tubes for dental aspiration, Sterile Internal and External Connection Dental Implant Systems, Sterile Narrow Body Dental Implant Systems.

This certificate is valid from Effective date 2023-01-26 until Expiry date 2026-01-25 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 2020-01-29

Authorised by Geofrey De Visscher Head of Notified Body 1639

SGS United Kingdom Ltd Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK t +44 (0)151 350-6666 - www.sgs.com

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.







