

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Lang Dental Manufacturing Co., Inc.  
175 Messner Drive  
Wheeling  
Illinois  
60090  
USA

Facility ID Number: F003071

Holds Certificate No:

**MDSAP 701281**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

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

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and manufacture of non-sterile acrylics, and pressure curing pots used in dental applications.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-01-04

Effective Date: 2023-11-02

Expiry Date: 2024-12-20



BSI Group America Inc. is an MDSAP recognised auditing organization