

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ASEPTICO INC.  
8333 216th Street SE  
Woodinville  
Washington  
98072  
USA

Facility ID Number: F003280

Holds Certificate No:

**MDSAP 705003**

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 Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806

Design, manufacture, and servicing of dental products including: powered dental drill, Gutta Percha delivery systems, portable dental units and orthodontic appliances.

Design and Contract Manufacturer of Subassemblies used in Active Medical Devices (non-implantable).

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-06-24

Effective Date: 2023-06-24

Expiry Date: 2026-06-23



BSI Group America Inc. is an MDSAP recognised auditing organization