

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ASO LLC
300 Sarasota Center Boulevard
Sarasota
Florida
34240
USA

Facility ID Number: F000055

Holds Certificate No: **MDSAP 694486**

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

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

Design, manufacture and distribution of wound care and first aid products: adhesive bandages, antibacterial bandages, non-adherent pads, nasal dilators, hydrocolloid bandages, wart freezer, hydrogel bandages and hemostatic gel. The distribution of: pads, medical tapes, dressings, gauze rolls, bandage rolls, cold/hot patch, wound cleanser, and wound closure strips. Adhesive coating of different substrates used in the manufacturing of adhesive bandages.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-01-19

Effective Date: 2025-09-13

Expiry Date: 2028-09-12



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP recognised auditing organization

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