

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Akunah Pty Ltd  
Suite 307, Level 9,  
Nicholson Street Specialist Centre,  
121 Newdegate Street, Greenslopes,  
Queensland  
4120  
Australia

Facility ID Number: F006341

Holds Certificate No:

**MDSAP 777351**

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

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

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

Design, Development, Manufacture and distribution of software for Orthopaedic Surgery.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-06-05

Effective Date: 2024-04-17

Expiry Date: 2026-05-21



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 1

...making excellence a habit.™