

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Advanced Medical Solutions Limited
Western Wood Way
Langage Science Park
Plymouth
Devon
PL7 5BG
United Kingdom

Facility ID Number: F000502

Holds Certificate No:

MDSAP 698701

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; 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, 21 CFR 807 - Subparts A to D

The design, development and manufacture of cyanoacrylate topical skin adhesives, cyanoacrylate skin sealants and cyanoacrylate wound protectants for use in the areas of general surgery and traumatic wound closure and cyanoacrylate topical skin protectants for over the counter use and for topical application and hernia mesh fixation.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-04-23

Effective Date: 2021-11-17

Expiry Date: 2024-11-16



BSI Group America Inc. is an MDSAP authorized auditing organization

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