



By Royal Charter

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Innovative Health Sciences, LLC  
1108 Kings Highway  
Suite #4  
Chester  
New York  
10918  
USA

Facility ID Number: F006287

Holds Certificate No:

**MDSAP 774917**

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

**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, development and manufacture of a syringe infusion system, syringe driver and subcutaneous needle sets.

For and on behalf of BSI:

  
\_\_\_\_\_  
Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-04-18

Effective Date: 2024-02-19

Expiry Date: 2025-12-11



BSI Group America Inc. is an MDSAP recognised auditing organization

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...making excellence a habit.<sup>TM</sup>

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

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