

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Shina Med Corporation
455-30
Bogaewonsam-ro
Bogae-myeon, Anseong-si
Gyeonggi-do
17509
Republic of Korea

Facility ID Number: F003476

Holds Certificate No:

MDSAP 705161

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

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

The design, development and manufacture of insulin syringe and insulin pen needle.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-07-16

Effective Date: 2022-07-03

Expiry Date: 2025-07-02



BSI Group America Inc. is an MDSAP recognised auditing organization

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