

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Shantou Wealy Medical Instrument  
Co., Ltd.  
North Jinhuan Road  
(near of Qishan Mid-school)  
Shantou  
Guangdong  
515064  
China

DUNS Number: 54-557-0186

Holds Certificate No:

**MDSAP 704920**

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

Design and manufacture of disposable safety syringe, disposable insulin safety syringe, disposable syringe (with needle) and disposable hypodermic needles.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-08-14

Effective Date: 2019-08-14

Expiry Date: 2022-08-13



BSI Group America Inc. is an MDSAP authorized auditing organization

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