

Certificate

Certificate No.: MD 2101141-1-1

Manufacturer: **Wujiang City Shen Ling Medical Device Co., Ltd.**
East of Building FS-02, No. 807 West Ganquan Road,
Jiangling Street, Wujiang District, Suzhou
215200 Jiangsu
P.R. China

REPs Facility ID: F005398

Certification criteria: ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure
Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
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
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and Development, Manufacture and Distribution of
Disposable Acupuncture Needles

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 326013140-200
Issue Date: 2024-07-18
Effective Date: 2024-07-18
Expiry Date: 2027-05-25



Certification officer: Herbert Zhong
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.