

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Providence Enterprise Limited

(FIN F005233)

Main Site: No.5-4 (Buildings 1-4, 7-8), Neihuan Ave, Shanxia Community, Pinghu, Longgang District, Shenzhen, Guangdong, P.R, China 518111

Additional site 1: No.6 (Buildings 1-5), Shankeng 1st Road, Shanxia Community Pinghu, Longgang District, Shenzhen, Guangdong, P.R, China 518111

Additional site 2: No.12, Neihuan Ave, Shanxia Community, Pinghu street, Longgang District, Shenzhen, P.R China 518111

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

### ISO 13485:2016

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

**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

**United States:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act [as applicable]

### The management system is applicable to:

*Contract manufacture and distribution of Oral Irrigators, Automatic Toothbrushes and accessories, Light Based Therapeutic Products, Nebulizers and accessories, Enuresis Alarms, Blood Lancets, Insulin Delivery Devices & Accessories, Stimulators, sterile and non-sterile Ophthalmic surgical devices.*

*Additional sites 1 and 2: Manufacturing*

**Certificate Number:**

0108866-02

**Initial Certification Date:**

2020-12-24

**Date of Certification Decision:**

2023-11-29

**Certification Effective Date:**

2023-12-23

**Certification Expiry Date:**

2026-12-23



intertek

**Calin Moldovean**

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