

CERTIFICATE OF CONFORMITY



Certificate number: **4240159**

Initial certification date: 12th September 2024

Certificate issue date: 12th September 2024

Certificate expiry: 11th September 2025

This is to certify the management system of

Nexgen Medsolutions Sdn. Bhd.

L-2-11, Plaza Damas, No. 60, Jalan Sri Hartamas 1, Sri Hartamas, 50480 Kuala Lumpur

has been registered by **LEADER** for the requirement of

MDA/RR No. 1 Good Distribution Practice for Medical Device (GDPMD)

Scope of certification:

Distribution (including Transportation), and Documentation (including Traceability of Medical Devices)

Device Category as per Annex 1

Outsourced activities: NA

Special storage: NA

Banredwan

MOHD IKRAM REDWAN

Leader Certification Sdn. Bhd. No 4-3 Jalan Seri Putra 1/1 Bandar Seri Putra Bangi, 43000 Kajang, Selangor, Malaysia





ANNEX 1 DEVICE CATEGORY

No.	Device Category
10	Single-use devices

- *List of device categories:
- 01 Active implantable devices
- 02 Anesthetic and respiratory devices
- 03 Dental Devices
- 04 Electro mechanical medical devices
- 05 Hospital hardware
- 06 In vitro diagnostic devices
- 07 Non-active implantable devices
- 08 Ophthalmic and optical devices
- 09 Reusable devices
- 10 Single-use devices
- 11 Assistive products for persons with disability
- 12 Diagnostic and therapeutic radiation devices
- 13 Complementary therapy devices
- 14 Biologically-derived devices
- 15 Healthcare facility products and adaptations
- 16 Laboratory equipment
- 17 Medical software
- 18 Others: Please specify with justification for any additional categories

