FDA CLEAN ROOM CLASSIFICATION CERTIFICATE

Certificate Number: CR-2023-PDR-1842

Issue Date: December 15, 2023

Expiration Date: December 14, 2024

Facility: Polar Dynamics Robotics, Inc.

Location: 4200 Innovation Drive, Newark, Delaware 19713

CERTIFICATION DETAILS

This certificate confirms that the clean room facilities at Polar Dynamics Robotics, Inc.'s primary manufacturing facility have been inspected and certified in accordance with ISO 14644-1:2015 and FDA Current Good Manufacturing Practice (cGMP) requirements.

CERTIFIED AREAS

Clean Room Suite A (Robot Assembly)

- **Classification:** ISO Class 6 (Fed Std 209E Class 1,000)
- **Total Area:** 2,500 square feet
- **Room Purpose:** Final assembly of medical-grade autonomous mobile robots
- **Monitoring System:** Continuous particle monitoring with real-time alert system
- **HVAC System:** Dedicated AHU-01 with HEPA filtration

Clean Room Suite B (Electronics Integration)

- **Classification:** ISO Class 7 (Fed Std 209E Class 10,000)
- **Total Area:** 1,800 square feet
- **Room Purpose:** Electronic component integration and testing
- **Monitoring System:** Scheduled particle monitoring with data logging
- **HVAC System:** Dedicated AHU-02 with HEPA filtration

TESTING METHODOLOGY

Testing conducted in accordance with ISO 14644-2:2015 using:

Met One HHPC-6+ Handheld Particle Counter

TSI 9110 Aerotrak Particle Counter

Validated environmental monitoring system

Parameters Tested:

- Airborne particle counts
- Air pressure differentials
- Temperature and humidity
- Air change rates
- HEPA filter integrity
- Air flow patterns
- Recovery time

COMPLIANCE SPECIFICATIONS

The certified areas maintain:

- Minimum of 30 air changes per hour
- Positive pressure differential of 0.05" w.g.
- Temperature range: 68 F 2 F
- Relative humidity: 45% 5%
- HEPA filtration efficiency: 99.99% at 0.3 microns

MONITORING REQUIREMENTS

Continuous Monitoring:

- Particle counts
- Differential pressure
- Temperature
- Relative humidity

Periodic Testing:

- HEPA filter integrity testing (semi-annual)
- Air flow visualization studies (annual)
- Microbial monitoring (monthly)
- Surface sampling (quarterly)

QUALITY CONTROL MEASURES

The facility maintains:

Environmental Monitoring Program (EMP-2023-12)

Clean Room Standard Operating Procedures (SOP-CR-2023)

Personnel Training Program (PTP-2023-04)

Contamination Control Strategy (CCS-2023-02)

CERTIFICATION AUTHORITY

This certification is issued by:

Advanced Cleanroom Certification Services, Inc.

FDA Registration #: 1234567890

ISO 17025 Accreditation #: AC-2345-US

COMPLIANCE STATEMENT

The above-described clean room facilities comply with:

- FDA 21 CFR Part 211
- ISO 14644-1:2015
- EU GMP Annex 1
- USP <797>

MAINTENANCE REQUIREMENTS

To maintain certification validity:

Quarterly performance verification

Semi-annual HEPA filter testing

Annual complete recertification

Continuous monitoring system validation

CERTIFICATION SIGNATURES

Lead Certifier:

/s/ Dr. Michael Thompson, P.E.

Clean Room Certification Engineer

License #: PE-78901

Quality Assurance Review:

/s/ Jennifer Martinez

Senior Quality Systems Manager

Certification #: QA-45678

Facility Representative:

/s/ Sarah Nordstrom

Chief Operating Officer

Polar Dynamics Robotics, Inc.

DISCLAIMERS

This certification is valid only for the specified areas and time period. Any modifications to the clean room facilities, HVAC systems, or control parameters may invalidate this certification. This certificate must be maintained with facility records and made available for regulatory inspection upon request.

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