Cleanroom Management Policy

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[Company Name], Inc.

Revision History

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1. Purpose

The purpose of this policy is to establish fundamental requirements for environmental management, contamination control, and work activities in cleanrooms in accordance with FDA Quality Management System Regulation (QMSR, 21 CFR Part 820) and ISO 13485:2016. This policy ensures product quality and patient safety through risk-based management of the work environment, thereby guaranteeing the safety and effectiveness of medical devices.

2. Scope

This policy applies to the management of all cleanrooms at the Company and work conducted within cleanrooms. It covers all manufacturing areas managed according to cleanroom cleanliness classifications defined in ISO 14644-1, and fulfills the requirements of ISO 13485:2016 Section 6.4 (Work Environment) and Section 7.5.2 (Cleanliness of Product).

3. Normative References

21 CFR Part 820 - Quality Management System Regulation (QMSR)

ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes

ISO 14644-1:2015 - Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration

ISO 14644-2:2015 - Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance

ISO 14644-3:2019 - Cleanrooms and associated controlled environments - Part 3: Test methods

ISO 14971:2019 - Medical devices - Application of risk management to medical devices

21 CFR Part 11 - Electronic Records; Electronic Signatures

4. Definitions

Term	Definition
Cleanroom	A room in which airborne particulate contamination is controlled to specified levels and, as necessary, temperature, humidity, and other parameters are controlled to specified standards.
QMSR	Quality Management System Regulation. FDA medical device quality regulation published as a final rule on February 2, 2024, effective February 2, 2026. Incorporates ISO 13485:2016 by reference and replaces the former QSR (Quality System Regulation).
Environmental Monitoring	Periodic measurement and recording of environmental parameters such as airborne particles, microorganisms, temperature, humidity, and differential pressure to monitor maintenance of cleanliness classification. Conducted in accordance with ISO 14644-2 and ISO 14644-3.
Alert Level	Warning level indicating that the process is beginning to deviate from normal operating conditions in environmental monitoring. When this level is exceeded, investigation and trend analysis are performed, and corrective actions are taken as necessary.
Action Level	Level indicating that immediate corrective action must be taken in environmental monitoring. When this level is exceeded, investigation begins immediately, and root cause analysis, impact assessment, and CAPA are implemented.
Gowning	The act of wearing cleanroom garments, caps, masks, gloves, shoe covers, etc., according to prescribed procedures when entering a cleanroom. Performed to