

Work Environment Management Procedure

Role	Position/Department	Name	Date
Author			DD YYYY
Reviewer			DD YYYY
Approver			DD YYYY

[Company Name], Inc.

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Revision History

Ver.	Effective Date	Revision Details (Reason, Changes, Affected Documents)	Author/Reviewer/Approver
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1. Purpose

The purpose of this document is to establish procedures for maintaining and managing the work environment for processes handling medical devices at [Company Name], Inc. (hereinafter referred to as the Company).

2. Scope

This document applies to the maintenance and management of work environments that affect the quality of medical device products handled by the Company. Cleanrooms are excluded from this scope and are covered separately in the Cleanroom Management Policy (MD-QMS-K73).

3. Definitions

Term	Definition
Assembly Area	Areas divided into assembly rooms, adjustment rooms, dust control rooms, etc., where product assembly, adjustment, and product inspection operations are performed.
Inspection Area	Areas divided into general inspection rooms and precision inspection rooms where receiving inspection and re-inspection of parts, in-process work, and products are performed.
Storage Area	Areas divided into general warehouses, specific warehouses, etc., where parts, in-process work, and products are stored.
ESD Prevention Equipment	Work benches equipped with electrostatic discharge (ESD) prevention measures through conductive mats, ground wires, wrist straps, etc.
Area B	Areas managed to cleanliness class 8 (ISO 14644-1) such as cleanroom anterooms and sterility test rooms.
Area C	General work rooms where cleanliness class 8 (ISO 14644-1) management is maintained.
Work Environment	As defined in 21 CFR § 820.70(b): 'Physical conditions such as temperature, humidity, cleanliness, and other environmental factors that could affect product quality.'
Environmental Monitoring	Systematic procedures to monitor and control work environment conditions to ensure they remain within specified limits as per QMSR requirements.

4. Roles and Responsibilities

Role	Responsibilities
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