Title

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

[Company Name], Inc.

Confidential

Revision History

Ver.	Effective Date Revision Details (Reason, Changes, Affected Documents) Author/Reviewer/Approver			
Version 1.0	**Effective Date**	20XXMM00DD00YYYY		
	Reason	Initial Release(For subsequent versions, describe the reason for revision here)		
	Content	Initial Release(For subsequent versions, describe the revision content here)		
	Affected Documents	N/A (For subsequent versions, list affected documents here)		
	役　　割	**Author**	**Reviewer**	**Approver**
	Department	XXX	XXX	XXX
	Position	XXX	XXX	XXX
	Name	XXX	XXX	XXX

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Term	Definition

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1. Purpose

The purpose of this policy is to establish requirements for the identification, calibration, maintenance, handling, and storage of all inspection, measuring, and test equipment (hereinafter referred to as "measuring equipment") used in the design, development, manufacturing, installation, and servicing of medical device products at [Company Name], Inc. (hereinafter referred to as "the Company"). This policy ensures compliance with 21 CFR Part 820.72 (QMSR) and ISO 13485:2016 clause 7.6.

2. Scope

This policy applies to all measuring equipment used throughout the product lifecycle, including design and development, incoming inspection, in-process inspection, final inspection, installation, and servicing of medical device products at the Company. This includes automated test equipment, computer software used for monitoring and measurement, and reference materials used for calibration purposes.

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 10012:2003 - Measurement management systems - Requirements for measurement processes and measuring equipment
ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories

4. Definitions

Term	Definition
Calibration	As defined in ISO 13485:2016, clause 3.3: "set of operations that establish, under specified conditions, the relationship between values indicated by a measuring system or values represented by a material measure, and the corresponding known values of a measurand."
Measuring Equipment	All inspection, measuring, and test equipment, including automated test equipment and software used for monitoring and measurement purposes, utilized in product realization processes to verify conformity to specified requirements.
Calibration Standard	A measurement standard used as a reference for calibration of measuring equipment, with documented traceability to national or international standards.
Traceability	As defined in 21 CFR 820.72(b)(1), the ability to trace calibration to national or international standards; where no such standards exist, the basis used for calibration shall be documented.
Calibration Status	The current state of calibration for measuring equipment, indicating whether equipment is calibrated and within its valid calibration period.
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled (ISO 13485:2016, clause 3.38).