Complaint Handling Policy

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

[Company Name], Inc.

Revision History

Ver.	Effective Date	Revision Details	Author/Reviewer/Approver	Affected Documents
1.0	DD MMM YYYY	Initial Release		N/A

Table of Contents

1. Purpose

The purpose of this policy is to establish requirements for the handling of complaints related to medical devices distributed by [Company Name], Inc. (hereinafter referred to as "the Company"). This policy ensures that complaints are received, evaluated, investigated, and resolved in a timely manner to:

a) Comply with applicable regulatory requirements including 21 CFR 820 (QMSR), ISO 13485:2016, EU MDR 2017/745, and other applicable regulations;

b) Identify potential safety issues and reportable events requiring Medical Device Reporting (MDR) to the FDA or vigilance reporting to other regulatory authorities;

c) Maintain customer satisfaction and confidence in Company products;

d) Drive continuous improvement in product quality through analysis of complaint trends.

2. Scope

This policy applies to all complaints received regarding medical devices manufactured, distributed, or serviced by the Company, including complaints related to product quality, safety, performance, labeling, and packaging. This policy covers complaints received from customers, healthcare professionals, patients, distributors, regulatory authorities, and any other sources.

3. Definitions

Term	Definition
Complaint	Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety, or performance of a medical device that has been released for distribution, or to a service that affects the performance of the device. (21 CFR 820.3(b) / ISO 13485:2016, 8.2.2)
Customer	An individual or organization that receives a product or service, or could receive a product or service. Examples include consumers, clients, end users, retailers, beneficiaries, and purchasers.
Evaluation	The process of collecting and reviewing information about a complaint, including the circumstances of the event, analysis of any returned product, lot information, manufacturing history, and market-related information.
Investigation	The process of determining the root cause of a complaint through systematic analysis.
MDR (Medical Device Report)	A report submitted to FDA when a manufacturer or importer becomes aware of information that reasonably suggests that a device marketed may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction were to recur. (21 CFR Part 803)
Reportable Event	An event that meets the criteria for reporting to regulatory authorities under applicable regulations (e.g., MDR requirements under 21 CFR 803, EU MDR vigilance reporting requirements).
SCAR	Supplier Corrective Action Request. A formal request to a supplier to investigate and correct a nonconformity attributable to their products or services.
Serious Injury	An injury or illness that: (1) is life-threatening; (2) results in permanent impairment of a body function or permanent damage to a body structure; or (3)