Quality Complaint / Post-Market Surveillance Form

This form is designed for the standardized reporting of all quality-related complaints, feedback, and adverse events associated with the use of a company's medical device or product within the post-market phase. It serves as a critical component of the quality management system, ensuring regulatory compliance and facilitating continuous product improvement.

Section 1: Reporter/Customer Information

This section is mandatory and must be completed accurately to ensure proper communication and follow-up regarding the reported issue.

Field	Description / Required Detail
Reporter/Customer Name	
Organization/Facility	
Title/Role	
Contact Phone Number	
Email Address	
Mailing Address	
Date of Report Submission	

Section 2: Product Identification

Accurate identification of the affected product is essential for investigation.

Field	Description / Required Detail
Product Name/Model	
Part Number/SKU	
Lot/Batch Number	
Serial Number (if applicable)	
Date of Manufacture	
Expiration Date (if applicable)	
Date of Installation/First Use	

Section 3: Complaint/Event Details

Detailed information regarding the nature and circumstances of the issue.

Field	Description / Required Detail
Date of Event Occurrence	
Location of Event	
Description of Complaint	
Was the Device Used as Intended?	
Action Taken Prior to Reporting	
Is the Product Available for Return?	
Was there Patient Harm or Injury?	
Was there Property Damage?	

-

Section 4: Adverse Event and Patient Outcome (Mandatory if Patient Harm Occurred)

Field	Description / Required Detail
Patient Identification	
Patient Outcome	
Description of Injury/Harm	
Relationship to Device	
Reporter's Qualification	

Section 5: Internal Use Only - QMS/Regulatory Assessment
(To be completed by Quality Assurance/Regulatory Affairs Personnel)

Field	Description / Required Detail
Complaint Log ID Number	
Initial Risk Assessment	
MDR/Vigilance Report Required?	
Investigation Lead	
Final Investigation Conclusion	
CAPA Required?	