|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **COMPLAINANT INFORMATION** | | | | | | | | | | | | | | | | **Complaint #:** | |  |
| Complaint Received by: | | |  | | | | | | | Date of Complaint: | | | |  | | | | |
| Name of Complainant: | | |  | | | | | | | Date of Report: | | | |  | | | | |
| Name of Institution: | | |  | | | | | | | Phone #: | | | |  | | | | |
| Street Address: | | |  | | | | | | | City/Zip Code: | | | |  | | | | |
| Email Address: | | |  | | | | | | | | | | | | | | | |
| Other Information: | | | | | | | | | | | | | | | | | | |
| **2. PRODUCT INFORMATION** | | | | | | | | | | | | | | | | | | |
| Product Name |  | | | | | | | | Model #/Part #: | | | |  | | | | | |
| Serial / Lot #: |  | | | | | | | | UDI Barcode: | | | | **DI:**  **PI:** | | | | | |
| **3. COMPLAINT DESCRIPTION** (including any injury and medical intervention) | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | |
| **Good Faith Effort** | | **Department Contacted** | | | | | | **Contact Name and Title** | | | | | | | **Date & Time** | | **Made Contact** | |
| 1st Attempted Contact | |  | | | | | |  | | | | | | |  | | Yes  No | |
| 2nd Attempted Contact | |  | | | | | |  | | | | | | |  | | Yes  No | |
| 3rd Attempted Contact | |  | | | | | |  | | | | | | |  | | Yes  No | |
| **4. INVESTIGATION** | | | | | | | | | | | | | | | | | | |
| *Is the device out of specification or was there a device malfunction?*   1. *If no, no further investigation, document rationale and decision maker’s name* 2. *If yes, is the deficiency identified as the same as that investigated before?*    1. *If no, investigate and document the root causes, reference historical data, Known Malfunction Lists, and FMEA to identify risk level*    2. *If yes, reference the previous complaint with documented investigation and close complaint, identify decision maker* | | | | | | | | | | | | | | | | | | |
| **MDR Decision Tree *(\* if yes to any of the below, the event must be reported)*** | | | | | | | | | | | | | | | | | | |
| **Is there death involved? \*** | | | | | | | | | | | | Yes  No | | | | | | |
| **Is there serious injury involved? \*** | | | | | | | | | | | | Yes  No | | | | | | |
| **Is there malfunction involved?** | | | | | | | | | | | | Yes  No | | | | | | |
| **If yes, should malf. recur would reasonably cause/contribute to D/SI? \*** | | | | | | | | | | | | Yes  No  N/A | | | | | | |
| **Note: \* If there is a yes to any of the questions above, file an MDR according to QP-0021 MDR procedure.** | | | | | | | | | | | | | | | | | | |
| **5. COMPLAINT RISK ASSESSMENT** | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | |
| **6. FURTHER ACTIONS** | | | | | | | | | | | | | | | | | | |
| Additional Disposition Information:  *Any associated CAPA/SCAR #’s:*  *Any Actions Taken to Prevent Recurrence*  *If No Actions Taken, Provide Rationale:* | | | | | CAPA #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  SCAR #: | | | | | | | | | | | | | |
| **7. REPLY TO COMPLAINANT** | | | | | | | | | | | | | | | | | | |
| Non-Verbal Complaint Communication: | | | | | | Yes, Attach | | | | | No | | | | | | | |
| Verbal Complaint Communication: | | | | | | Yes, Document & Attach | | | | | No | | | | | | | |
| **8. APPROVALS** | | | | | | | | | | | | | | | | | | |
| **Department** | | **Required?** | | | | | **Signature** | | | | | | | | | | **Date** | |
| Quality Assurance | | Yes | | No | | |  | | | | | | | | | |  | |
| Engineering | | Yes | | No | | |  | | | | | | | | | |  | |