**Product Quality Incident Description**

F-QA&R-005-001-12

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| **Reporter information** | |
| **Name** |  |
| **Designation / Assignment** |  |
| **Email** |  |
| **Organization** |  |
| **Country** |  |

|  |  |
| --- | --- |
| **Location information** | |
| **Site Name[[1]](#footnote-1)** |  |
| **City & Country** |  |
| **Date Discovered** |  |
| **Discovered by Whom** |  |

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| **Product information** | |
| **Product name** |  |
| **Batch/Lot/Serial No** |  |
| **Manufacturer** |  |
| **Manufacturing site Address** |  |
| **Supplier (if different from the manufacturer)** |  |
| **PO number (if known)** |  |
| **ASN (if known)** |  |
| **Manufacturer’s catalogue no (if applicable)** |  |
| **Associated devices & accessories (if applicable)** |  |
| **UOM** |  |
| **Total quantity received (in UOM)** |  |
| **Number of Units[[2]](#footnote-2) Affected** |  |
| **Quality Complaint** | Leaky packaging / containers  Damaged or crushed boxes (pallet/shipper cartons/inner packaging)  Wet boxes (with any liquid)  Unusual color or odor of the product  Incorrect or missing labeling  Incorrect instructions for use (IFU)  Temperature excursion during transportation  Missing components in a kit  Malfunction or deterioration in the performance of diagnostics  Out of specification detected during QC testing  Adverse drug reaction or event reported by patients  Other (please specify): |
| **Detailed description of the quality complaint:** |  |

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| **Measures Taken** | |
| **Describe which of the following actions have been taken** | Discontinued use  Quarantine of affected lots  Notification of relevant authorities  Notification of relevant customers  Other (please specify): |
| **Confirmation of quarantine (tick if applicable)** | We hereby confirm that \_\_\_\_\_\_\_\_ (quantity) of the product has been kept under quarantine at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of warehouse) till such time the investigation is over and we have received clearance from PFSCM. |
| **Any additional comments:** |  |

|  |  |
| --- | --- |
| **Signature** |  |
| **Date** |  |

**Photos Attached (Preferred):**   Yes  No

Please send your completed form to [productquality@pfscm.org](mailto:productquality@pfscm.org)

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1. Can be a warehouse or health facility. If there are multiple locations, please name them all. [↑](#footnote-ref-1)
2. If more than one batch is affected, specify quantity per batch [↑](#footnote-ref-2)