**Product Quality Incident Description**

F-QA&R-005-001-12

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

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| **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:** |  |

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

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

Please send your completed form to productquality@pfscm.org

F-QA&R-005-001-12

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)