|  |  |  |
| --- | --- | --- |
|  | | **FK ref. number** |
| **Report date \*: / / 20** |  |  |

Send this form back to email-address : [bene.complaints@fresenius-kabi.com](mailto:bene.complaints@fresenius-kabi.com) \* **Fields marked with \* are mandatory**

**ONLY 1 BATCH PER REPORT**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **A. CUSTOMER REFERENCES** | | | | | | | | |
| 1. Customer number: | |  | **2. Organisation/Company:\*** | | |  | | |
| **3.** **Zipcode: \*** | |  | **4. Street:\*** | | |  | | |
| **5. City:\*** | |  | | | | 6. Customer complaint ref.: | |  |
| **7. Contact person:** **\*** | |  | | | | **8. Tel. nr contact person:\*** | |  |
| **9. E-mail contact person:\*** | |  | | | | | | |
| **B. COMPLAINT DESCRIPTION** | | | | | | | | |
| **1. Product (name, strength, volume, ..):\*** | | | |  | | | | |
| **2. Article / Material number: \*** | | | |  | | **3. Batch number: \*** |  | |
| **4**. Date of complaint observation**:** | | | |  | | | | |
| **5. Description of complaint (BE DETAILED !): \*** | | | | | | | | |
| **6. Timing of complaint observation \*** | | | | before unpacking  after unpacking,  but before usage  during usage   (add details in next cell) | **Details on timing**  (e.g. pharma: after what administered dose – medical device: after how much time, at which step in a complex procedure, etc…) | | | |
| **7. Number of units that presented the same defect: \*** | | | | | |  | | |
| **8. Attachments (photo, drawing,...):** \* | | | | no  yes | | | | |
|  | | | | If Yes, amount + description:  (please add photo while defect occurs) | |  | | |
| 9. Did the complaint result in an ADR or  incident causing death or causing a  severe deterioration of the state of health  of a patient or user? | | | | no  yes | | | | |
|  | | | | If Yes, describe:  Please also send copy of report to [bene.vig@fresenius-kabi.com](mailto:bene.vig@fresenius-kabi.com) | |  | | |
| **C. COMPLAINT SAMPLES** | | | | | | | | |
| **1. Complaint samples available for**  **eventual further investigation** \*  **(Only defect samples !!)** | | | | no  yes | | | | |
|  | | | | If Yes, , amount: | |  | | |
| **2. Condition of the complaint samples:\*** | | | | unused  used | | | | |
| **3. Sample possibly infectious (blood): \*** | | | | no  yes (if yes, serological attest needed for sample pick-up) | | | | |
| **4. Sample used with cytostatics: \*** | | | | no  yes | | | | |
| 5. Remarks : |  | | | | | | | |
| **ATTACH THIS COMPLAINT REPORT TO SAMPLES THAT ARE RETURNED FOR INVESTIGATION !!**  **RETURNED SAMPLES NEED TO BE DULY PACKAGED i.e. SAFE AND LEAKPROOF!** | | | | | | | | |