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

 Send this form back to email-address : 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  |  |
| **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!** |