|  |  |  |  |
| --- | --- | --- | --- |
| **Sender information** | | | |
| **Name and address of Certificate Holder**  (Legal Manufacturer) | Please indicate here the exact company name and address | | |
| **Applicable Scheme** | MDR  IVDR | MDD  IVDD | UK MDR (MDD-based)  UK MDR (IVDD-based) |
| **Certificate Number** | Indicate here the number of the certificate affected by the incident | | |
| **Manufacturing Facility**  (if applicable) | Insert here the name and address of the manufacturing facility (if different from above) | | |
| **Your Reference No. for the incident** | Enter reference number (if applicable) | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Incident Information** | | | | | |
| **Product name** | | | Please indicate the brand name of the product | | |
| **Generic device group under MDR/IVDR** | | | Please indicate the generic device group (EMDN), 4th level | | |
| **Generic device group / under MDD/IVDD or**  **UK MDR (MDD-based/**  **IVDD-based)** | | | Please indicate generic device group, by GMDN or EDMS code or by any other term describing the relevant product group | | |
| **Kind of incident** | | | Describe in one word or sentence the type of the incident (please keep it short) | | |
| **Classification of measures** | | | Manufacturing defect  Isolated vigilance case  Recall  Labelling  User failure  Others: Please specify | | |
| **Are measures planned as a result of the incident?** | | | **Please select an item** | | |
| **Do you see a trend for this kind of incident?** | | | yes  no | | |
|  | | YYYY-MM-DD |  | | enter name here; no need for signature |  | |
|  | | **Date** |  | | **Name** |  | |

Please send the completed checklist to [medical-vigilance@tuv.com](mailto:markcheck@tuv.com)

You will receive a confirmation email with the identification number of this case in brackets in the subject line.

For all related communication please always use this identification number in your e-mail subject line.