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| **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) |

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| **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

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.