**MANUFACTURER IVD INCIDENT INVESTIGATION REPORTING FORM**

Reporting form to be sent by manufacturer to the national regulatory authority where the incident occurred when they are notified of a problem with potential for public health impact by a user/testing provider.

**1. Reporter details**

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| Name of recipient organization (NRA): | |
| Street Name and No.: | City and postcode: |
| Country: | Telephone: |
| Name and position of recipient contact person: | Email of contact person: |
| Identifier assigned by the manufacturer: | Identifier assigned by NRA: |
| Type of report:  ❑ Initial report  ❑ Follow-up report  ❑ Combined initial and final report  ❑ Final report | State any other NRAs who were also sent this report: |

**2. Reporter manufacturer details**

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| --- | --- |
| Name of reporting manufacturer: | |
| Street Name and No.: | City and postcode: |
| Country: | Telephone: |
| Name of contact person: | Email of contact person: |

**3. Product details**

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| Product name: |
| Product code/catalogue number(s): |
| Lot number/batch number/serial number (s): |
| Expiry date(s): |
| Associated devices/accessories (lot numbers/expiry dates): |
| Instructions for use version number: |
| Software version number (if applicable): |
| Unique device identifier - device identifier (UDI-DI)/unique device identifier- production identifier (UDI-PI): |
| Falsification status check:  ❑ Genuine  ❑ Manipulated  ❑ Falsified |

Please attach a copy of the instructions for use.

**4. Event details**

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| Where did the observation/event happen: | |
| Date(s) observation/event happened: | |
| Date feedback reported to manufacturer (and/or economic operator) by user: | |
| Event/problem description narrative (explain what went wrong with the product, and a description of the health effects [if applicable], i.e. clinical signs, symptoms, conditions as well as the overall health impact [death, life-threatening, indirect harm]), and the health/medical condition for which the device was used: | |
| IMDRF Medical Device Problem Code(s) (Annex A): | |
| IMDRF Medical Device Component (Annex G): | |
| User at the time of the event/problem  (please choose):  ❑ Healthcare professional/lay provider:  ❑ Patient/client:  ❑ Other (specify): | Has more than one user experienced the problem  with the product?  ❑ Yes ❑ No |
| Number of devices involved: | Number of patients involved: |
| IMDRF Clinical Sign Codes (Annex E): | IMDRF Health Impact Codes (Annex F): |

**5. Manufacturer’s preliminary comments (initial/follow-up reports)**

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| Manufacturer’s preliminary analysis of event: |
| IMDRF Type of Investigation (Annex B): |
| IMDRF Investigation Findings (Annex C): |
| Initial correction implemented by manufacturer: |
| Expected date of next report: |

**6. Results of the final investigation (final report)**

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| Manufacturer’s analysis of event: |
| IMDRF Type of Investigation (Annex B): |
| IMDRF Investigation Findings (Annex C): |
| IMDRF Investigation Conclusion (Annex D): |
| Any additional corrections implemented by manufacturer: |
| Corrective action/preventive action implemented by manufacturer: |
| Field safety corrective action by manufacturer: |
| Date field safety notice issued: |
| Field safety notice identifier: |
| Time schedule for implementation of the identified actions: |
| Final comments from the manufacturer: |
| Further investigations, including analysis of other impacted areas: |
| Is the manufacturer aware of similar events with this IVD with a similar root cause?  ❑ Yes ❑ No |
| If yes, state in which countries:  If yes, number of similar incidents: |
| State which countries this report has been disseminated to: |

**7. Signature**

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| Name: |
| Signature: |
| Date: |

Disclaimer: The act of reporting an observation is not an admission of manufacturer, user or patient liability for the event or its consequences. Reporting incidents and serious public health threats in itself, represent a conclusion by the manufacturer that the content of this report is complete or confirmed, that the device(s) listed failed in any manner. It is also not a conclusion that the device caused or contributed to the incident.