**Instruction:** Please fill in the form and attach document if necessary.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SAE report | |  SAE event  Device Defect | | | | | | | | |  |
| Protocol title | |  | | | | | | | | | **IRB NO.**  \_\_\_\_\_\_ |
| Report type | | * Initial  Follow-up No................. * Final  Other …………………………. | | | | | | | | | |
| **1. Company information (If available)** | | | | | | | | | | | |
| Establishment License No./Seller's License No. | | | | | |  | | | | |  |
| Company’s name | |  | | | | | | | | | |
| Address | |  | | | | | | | | | |
| Reporter | |  | | | | | Position |  | | | |
| Telephone No. | |  | | | | | E-mail |  | | | |
| Other regulatory authorities to which this report was also sent. | | | | | | | | | | | |
|  | | | | | | | | | | | |
| **2. Device details** | | | | | | | | | | | |
| Trade name | |  | | | | | | | | | |
| Common name | |  | | | | | | | | | |
| Global Medical Device Nomenclature  (GMDN) code | |  | | | | | | | | | |
| Type of medical device | | * IVD * Non-IVD | | Risk classification | * Class I  Class II * Class III  Class IV | | | | | | |
| Indication/intended use | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Device regulatory status | | * Licensed medical device No. ………………………………………..………….….…………………..…............…..………… * Notified medical device No. …………….………………………………………………………………………….…………...….. * Listed medical device No. .......................................................................................................................... * Other, specify ................................................................................................................................................. | | | | | | | | | |
| Catalogue No. |  | | Model No. | |  | | | | Lot/Batch No. |  | |
| Serial No. |  | | Software version | |  | | | | | | |
| Accessories | |  | | | | | | | | | |
|  | |  | | | | | | | | | |
| Physical manufacturer | |  | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- |
| **3. Information of serious adverse event / device defect** | | | | | |
| Classification of incident | |  Serious threat to public health   Death   Serious injury | | | |
| Medical device problem | |  | | | |
|  | | | |
|  | | | |
| Clinical sign, symptoms and conditions | |  | | | |
|  | | | |
|  | | | |
| Event description | | | | | |
|  | | | | | |
| Date of incident |  | | | awareness date |  |
| Have any of the similar events occurred? | * Yes, specify the country ................................................................................................... * No * Unknown | | | | |
| Have any of other AE occurred by using the medical device for the same cause? | | | * Yes, country .....................................................................................   frequency of occurrence ……………......................................   * No  Unknown | | |
| User of device at the time of the event | * Healthcare professional * Patient Other, specify ....................................................................................................... | | | | |
| Usage of device | * Initial use * Reuse of a single use device * Reuse of a reusable device * Re-service/Refurbished * Other, specify ....................................................................................................................... | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Number of patients involved |  | Number of devices involved |  |

|  |  |
| --- | --- |
| 4. **Patient information (only for serious adverse event))** | |
| Gender |  Male  Female  Unknown |
| Age at time of the incident | ........................... (year/month/day)  Unknown |
| Health impact |  |
| <https://www.imdrf.org/working-groups/adverse-event-terminology/annex-f-health-effects-health-impact> |
| Treatment of affected person | |
|  | |
| Patient outcome | * Death (Date: ......../......../.........) * Not yet recovered * Recovered (Date: ......../......../.........) * Other, specify .................................................................................................................... |

|  |
| --- |
| 5. **Other information** |
|  |

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| --- |
| Investigator’s signature ……..…….....................…...…...................................... Date…….....…..…/…….....…..…/…….....…..…  ……………........................…...................................................................................... (Print Name and Surname) |