**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  |   |

|  |
| --- |
| **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**  |
|   |

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