|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| The reporting form is textual derived to MEDDEV2.12/1rev8. | | | | |
| **Classification of incident** | | | | |
| Serious public health threat  Death  Unanticipated serious deterioration in state of health  All other reportable incidents | | | | |
|  | | | | |
| **Who reporting** | | | | |
| Internal name MP consultant: | |  | | |
| External name: | | | E-mail: | |
| Address: | | | Phone: | |
| ZIP: | | | City: | |
| Country: | | |  | |
|  | | | | |
| **Medical device information** | | | | |
| AIMD Active implants  MDD/MDR Class III  MDD/MDR Class IIb  MDD/MDR Class IIa  MDD/MDR Class I or  MDR Class Ir | | |  | |
|  | | | | |
| Nomenclature system (GMDN/UMDNS): | | | Nomenclature code: | |
| Nomenclature text: | | | | |
| Commercial name/brand name/make: | | | | |
| Model number: | | | Catalogue number: | |
| Serial number(s) (if applicable): | | | Lot/batch number (if applicable): | |
| UDI: | | | | |
| UDI-DI (01): |  | | UDI-PI (10) or (21): |  |
| Software version number (if applicable): | | | | |
| Device Manufacturer Date: | | | Expiry date (falls zutreffend): | |
| Implant date (For implants only): | | | Explant date (For implants only): | |
| Duration of Implantation (For implants only. To be filled if the exact implant and explant dates are unknown): | | | | |
| Accessories/associated devices (if applicable): | | | | |
| Notified Body (NB) ID-number:  mdc 0483 | | | | |
|  | | | | |
| **Incident information** | | | | |
| Date the incident occurred: | | | | |
| Incident description narrative: | | | | |
| User facility report reference number (if applicable): | | | | |
| Manufacture’s awareness date: | | | | |
| Number of patients involved (if known): | | | Number of medical devices involved (if known): | |
| Medical device current location/disposition (if known): | | | | |
| Operator of the medical device at the time of incident (select one):  Healthcare Professional  Patient  Lay uder  Other, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| Usage of the medical device (select from list below):  Initial use  Reuse of a single use medical device  Reuse of reusable medical device  Other:  Problem noted prior use | | | | |
|  | | | | |
| **Patient information** | | | | |
| Patient outcome: | | | | |
| Remedial action taken by the healthcare facility relevant to the care of the patient: | | | | |
| Gender (if applicable):  Female  Male | | | | |
| Age of the patient at the time of incident (if applicable): | | | | |
| Weight in kilograms (if applicable): | | | | |
|  | | | | |
| **Healthcare facility information** | | | | |
| Name of the healthcare facility: | | | | |
| Contact person: | | | | |
| Address: | | | | |
| ZIP: | | | City: | |
| Phone: | | | Fax: | |
| E-mail: | | | Country: | |