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| 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: |