# Report Form

**Manufacturer’s Incident Report**

Medical Devices Vigilance System  
(MEDDEV 2.12/1 rev 5)

## 1. Administrative information

<table>
<thead>
<tr>
<th>Recipient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name of national competent authority (NCA)</strong></td>
</tr>
<tr>
<td><strong>Address of national competent authority</strong></td>
</tr>
<tr>
<td><strong>Date of this report</strong></td>
</tr>
<tr>
<td><strong>Reference number assigned by the manufacturer</strong></td>
</tr>
<tr>
<td><strong>Reference number assigned by NCA to whom sent (if known)</strong></td>
</tr>
</tbody>
</table>

### Type of report

- Initial report
- Follow-up report
- Combined initial and final report
- Final report

### Classification of incident

- Death or unanticipated serious deterioration in state of health, serious public health threat
- All other reportable incidents

Identify to what other NCAs this report was also sent

## 2. Information on submitter of the report

<table>
<thead>
<tr>
<th>Status of submitter</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Manufacturer</td>
</tr>
<tr>
<td>☐ Authorised representative within EEA and Switzerland</td>
</tr>
<tr>
<td>☐ Others (identify the role):</td>
</tr>
</tbody>
</table>

## 3. Manufacturer information

<table>
<thead>
<tr>
<th>Manufacturer name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer’s contact person</td>
</tr>
<tr>
<td><strong>Address</strong></td>
</tr>
<tr>
<td><strong>Postal code</strong></td>
</tr>
<tr>
<td><strong>Phone</strong></td>
</tr>
<tr>
<td><strong>E-mail</strong></td>
</tr>
</tbody>
</table>

## 4. Authorised Representative information

<table>
<thead>
<tr>
<th>Name of the authorised representative</th>
</tr>
</thead>
<tbody>
<tr>
<td>The authorised representative’s contact person</td>
</tr>
<tr>
<td><strong>Address</strong></td>
</tr>
<tr>
<td><strong>Postal code</strong></td>
</tr>
<tr>
<td>Phone</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>E-mail</td>
</tr>
</tbody>
</table>

### 5 Submitter's information (if different from section 3 or 4)

- **Submitter's name**
- **Name of the contact person**
- **Address**
- **Postal code**
- **City**
- **Phone**
- **Fax**
- **E-mail**
- **Country**

### 6 Medical device information

- **Class**
  - [ ] AIMD Active implants
  - [ ] MDD Class III
  - [ ] MDD Class IIb
  - [ ] MDD Class IIa
  - [ ] MDD Class I
  - [ ] IVD Annex II List A
  - [ ] IVD Annex II List B
  - [ ] IVD Devices for self-testing
  - [ ] IVD General
- **Nomenclature system (preferable GMDN)**
- **Nomenclature code**
- **Nomenclature text**
- **Commercial name/brand name/make**
- **Model and/or catalogue number**
- **Serial number(s) and/or lot/batch number(s)**
- **Software version number (if applicable)**
- **Manufacturing date/expiry date (if applicable)**
- **Accessories/associated device (if applicable)**
- **Notified body (NB) ID- number**

### 7 Incident information

- **User facility report reference number, if applicable**
- **Manufacturers awareness date**
- **Date of incident occurred**
- **Incident description narrative**
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)
- health care professional
- patient
- other
Usage of the medical device (select from list below)
- initial use
- reuse of a reusable medical device
- reuse of a single use medical device
- re-serviced/refurbished
- problem noted prior use
- other (please specify):

8 Patient information
Patient outcome
Remedial action taken by the healthcare facility relevant to the care of the patient
Age of the patient at the time of incident, if applicable
Gender, if applicable
- Female
- Male
Weight in kilograms, if applicable

9 Healthcare facility information
Name of the healthcare facility
Contact person within the facility
Address
Postal code | City
Phone | Fax
E-mail | Country

10 Manufacturer’s preliminary comments (Initial/Follow-up report)
Manufacturer’s preliminary analysis
Initial corrective actions/preventive actions implemented by the manufacturer
Expected date of next report

11 Results of manufacturers final investigation (Final report)
The manufacturer’s device analysis results
Remedial action/corrective action/preventive action/Field Safety Corrective Action
*NOTE: In the case of a FSCA the submitter needs to fill in the form of Annex 4*
Time schedule for the implementation of the identified action

Final comments from the manufacturer

Further investigations

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

☐ Yes    ☐ No

If yes, state in which countries and the report reference numbers of the incidents

For final report only. The medical device has been distributed to the following countries:

Within EEA and Switzerland:

☐ AT  ☐ BE  ☐ BG  ☐ CH  ☐ CY  ☐ CZ  ☐ DE  ☐ DK  ☐ EE  ☐ ES

☐ FI  ☐ FR  ☐ GB  ☐ GR  ☐ HU  ☐ IE  ☐ IS  ☐ IT  ☐ LI  ☐ LT

☐ LU  ☐ LV  ☐ MT  ☐ NL  ☐ NO  ☐ PL  ☐ PT  ☐ RO  ☐ SE  ☐ SI

☐ SK

Candidate Countries:

☐ HR  ☐ TR

☐ All EEA, Candidate Countries and Switzerland

Others:

12 Comments

I affirm that the information given above is correct to the best of my knowledge.

Signatures

Name City Date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.