V.05/07

Report Form
Manufacturer's Incident Report

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

1. Administrative information **Recipient**
Name of national competent authority (NCA)
Address of national competent authority
Date of this report
Reference number assigned by the manufacturer
Reference number assigned by NCA to whom sent (if known)
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
Status of submitter ☐ Manufacturer ☐ Authorised representative within EEA and Switzerland ☐ Others (identify the role):

3 Manufacturer information	
Manufacturer name	
Manufacturer's contact person	
Address	
Postal code	City
Phone	Fax
E-mail	Country

4 Authorised Representative information	
Name of the authorised representative	
The authorised representative's contact person	
Address	
Postal code	City

Phone	Fax
E-mail	Country

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 ☐ other (please specify):	☐ reuse of a single use medical device ☐ re-serviced/refurbished ☐ problem noted prior use

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 ☐ BU ☐ 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:

☐ CR ☐ 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.

.....
Signature

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.