import XML

fill with test data Initial

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fill with test data Follow Up

fill with test data Final

Report Form
Manufacturer's Incident Report
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 6)

new case, keep base data

Version E2.08
2010-06-08

1 Administrative information

Recipient (Name of NCA)	Stamp box
Address of National Competent Authority	

Date of this report

Reference number assigned by the manufacturer

Reference number assigned by NCA

Type of report

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

Does the incident represent a serious public health threat?

- ◯ yes
- ◯ no

Classification of incident

- ◯ Death
- ◯ Unanticipated Serious Deterioration in State of Health
- ◯ All other reportable incidents

Identify to what other NCA's 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

new

Name	
Contact Name	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country**

4 Authorised Representative Information

new

Name of the Authorised Representative	
The Authorised Representative's contact person	
Address	
Postal code	**City**
Phone	**Fax**
E-mail	**Country**

5 Submitter’s information

new

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

6 Medical device information

new

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**
GMDN	

Nomenclature text

Commercial name/ brand name / make

Model number	**catalogue number**

Serial number(s) (if applicable)	**Lot/batch number(s) (if applicable)**

Software version number (if applicable)

Device Mfr Date	**Expiry date**

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

7 Incident Information

Date the incident occurred

Incident description narrative

User facility report reference number, if applicable

Manufacturer's awareness date

Number of patients involved (if known)	**Number of medical devices involved (if known)**
0	1

Medical device current location/disposition (if known)

Operator of the medical device at the time of incident (select one)

- ◯ Healthcare Professional
- ◯ Patient
- ◯ Other

Usage of the medical device (select from list below)

- ◯ initial use
- ◯ reuse of a single use medical device
- ◯ reuse of a reusable medical device
- ◯ re-serviced/refurbished
- ◯ other
- ◯ problem noted prior use

8 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	units ◯ Years ◯ months ◯ days

Weight in kilograms, if applicable

9 Healthcare facility information

new

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
Time schedule for the implementation of the identified actions
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
Number of similar incidents 0
If yes, state in which countries and the report reference numbers of the incidents.

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

within the 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

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised 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.

Signature

print form

send XML-data by E-Mail

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