

10.3 ANNEX 3 REPORT FORM FOR MANUFACTURER'S TO THE NATIONAL COMPETENT AUTHORITY

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	
<input type="checkbox"/> Initial report	
<input type="checkbox"/> Follow-up report	
<input type="checkbox"/> Combined initial and final report	
<input type="checkbox"/> Final report	
Classification of incident	
<input type="checkbox"/> Death or unanticipated serious deterioration in state of health, serious public health threat	
<input type="checkbox"/> All other reportable incidents	
Identify to what other NCAs this report was also sent	

2 Information on submitter of the report	
Status of submitter	
<input type="checkbox"/> Manufacturer	
<input type="checkbox"/> Authorised representative within EEA and Switzerland	
<input type="checkbox"/> 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	
<input type="checkbox"/> AIMD Active implants	
<input type="checkbox"/> MDD Class III	<input type="checkbox"/> IVD Annex II List A
<input type="checkbox"/> MDD Class IIb	<input type="checkbox"/> IVD Annex II List B
<input type="checkbox"/> MDD Class IIa	<input type="checkbox"/> IVD Devices for self-testing
<input type="checkbox"/> MDD Class I	<input type="checkbox"/> 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)	
<input type="checkbox"/> health care professional	
<input type="checkbox"/> patient	
<input type="checkbox"/> other	
Usage of the medical device (select from list below)	
<input type="checkbox"/> initial use	<input type="checkbox"/> reuse of a single use medical device
<input type="checkbox"/> reuse of a reusable medical device	<input type="checkbox"/> re-serviced/refurbished
<input type="checkbox"/> other (please specify):	<input type="checkbox"/> 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
<input type="checkbox"/> Female <input type="checkbox"/> 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.

.....
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.