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

v.01.13

Report Form
Manufacturer's Incident Report

Medical Devices Vigilance System

(MEDDEV 2.12/1 rev 8)

1. Administrative information	
Recipient Name of National Competent Authority (NCA) Address of National Competent Authority	**Stamp box for the Competent Authority (~ 60 x 40 mm)**
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 NCAs this report was **also** sent	
2. Information on submitter of the report	
Status of submitter ☐ Manufacturer ☐ Authorised Representative within EEA, Switzerland and Turkey ☐ Others: (identify the role) :	

3. Manufacturer information	
Name	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
4. Authorised Representative information	
Name	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
5. Submitter's information (if different from section 3 or 4)	
Submitter's name	
Contact name	
Address	
Postcode	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 number	Catalogue number
Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)
Software version number (if applicable)	
Device Manufacturing date	Expiry date
Implant date (for implants only)	Explant date (for implants only)
Duration of implantation (to be filled is the exact implant or explant dates are unknown)	
Accessories/ associated device (if applicable)	
Notified Body (NB) ID-number	

7. Incident information

User facility report reference number, if applicable	
Manufacturers awareness date	
Date the 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 single use medical device

☐ reuse of a reusable medical device ☐ re-serviced/refurbished

☐ other (please specify)

☐ 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 health care facility
Contact person within the facility
Address

Postcode	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 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.
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, Switzerland and Turkey:

☐ 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	☐ TR	☐ HR							

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:

12. Comments

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.

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

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Name City date