Ref. Ares(2016)856772 - 18/02/2016

Report Form
Manufacturer's Trend Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

v.12/11

1. Administration 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	
Type of report ☐ Trend Initial ☐ Trend Follow up ☐ Trend Final	
Do these incidents / trend represent a serious public health threat? ☐ Yes ☐ No	
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(s) or Family name	Catalogue number(s)
Serial number range (if applicable)	Lot/batch number range(if applicable)
Software version number (if applicable)	
Accessories / associated devices (if applicable)	

Notified Body (NB) ID – Number
7. Information on Trend Report
Date the trend was identified
Description narrative for identified trend
Time period of trend analysis
Established trigger level
Have any of the trended events been submitted individually as reportable events under vigilance? ☐ Yes ☐ No
If yes, please list how many and to which Competent Authority
8. Manufacturer's preliminary comments
Manufacturer's preliminary analysis into causes of trend
Initial corrective actions / preventive actions implemented by the manufacturer
Expected date of next report
9. Results of manufacturer's final investigation into trend
The manufacturer's trend analysis results
Remedial action / corrective action / preventive action / Field Safety Corrective Action
Time scheduled for the implementation of the identified actions
Final comments from the manufacturer
Further investigation
10. 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 Candidate Countries: ☐ HR ☐ All EEA, Candidate Countries, Switzerland and Turkey Others:
11. 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.

…….

Name City date