

**10.7 ANNEX 7- MANUFACTURER'S TREND REPORT FORM**

**Report Form  
Manufacturer's Trend Report  
Medical Devices Vigilance System (MEDDEV 2.12/1 rev 8)**

v. 01.13

<b>1. Administration Information</b>	
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 <input type="checkbox"/> Trend Initial <input type="checkbox"/> Trend Follow up <input type="checkbox"/> Trend Final	
Do these incidents / trend represent a serious public health threat? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Identify to what other NCAs this report was <b>also</b> sent	
<b>2. Information on submitter of the report</b>	
Status of submitter <input type="checkbox"/> Manufacturer <input type="checkbox"/> Authorised Representative within EEA, Switzerland and Turkey <input type="checkbox"/> Others: (identify the role) :	
<b>3. Manufacturer information</b>	
Name	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
<b>4. Authorised Representative information</b>	
Name	

Contact name											
Address											
Postcode	City										
Phone	Fax										
E-mail	Country										
<b>5. Submitter's information (if different from section 3 or 4)</b>											
Submitter's name											
Contact name											
Address											
Postcode	City										
Phone	Fax										
E-mail	Country										
<b>6. Medical Device Information</b>											
<p><b>Class</b></p> <table border="0"> <tr> <td><input type="checkbox"/> AIMD Active Implants</td> <td><input type="checkbox"/> IVD Annex II List A</td> </tr> <tr> <td><input type="checkbox"/> MDD Class III</td> <td><input type="checkbox"/> IVD Annex II List B</td> </tr> <tr> <td><input type="checkbox"/> MDD Class IIb</td> <td><input type="checkbox"/> IVD Devices for self-testing</td> </tr> <tr> <td><input type="checkbox"/> MDD Class IIa</td> <td><input type="checkbox"/> IVD General</td> </tr> <tr> <td><input type="checkbox"/> MDD Class I</td> <td></td> </tr> </table>		<input type="checkbox"/> AIMD Active Implants	<input type="checkbox"/> IVD Annex II List A	<input type="checkbox"/> MDD Class III	<input type="checkbox"/> IVD Annex II List B	<input type="checkbox"/> MDD Class IIb	<input type="checkbox"/> IVD Devices for self-testing	<input type="checkbox"/> MDD Class IIa	<input type="checkbox"/> IVD General	<input type="checkbox"/> MDD Class I	
<input type="checkbox"/> AIMD Active Implants	<input type="checkbox"/> IVD Annex II List A										
<input type="checkbox"/> MDD Class III	<input type="checkbox"/> IVD Annex II List B										
<input type="checkbox"/> MDD Class IIb	<input type="checkbox"/> IVD Devices for self-testing										
<input type="checkbox"/> MDD Class IIa	<input type="checkbox"/> IVD General										
<input type="checkbox"/> MDD Class I											
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											
<b>7. Information on Trend Report</b>											

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? <input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, please list how many and to which Competent Authority
<b>8. Manufacturer's preliminary comments</b>
Manufacturer's preliminary analysis into causes of trend
Initial corrective actions / preventive actions implemented by the manufacturer
Expected date of next report
<b>9. Results of manufacturer's final investigation into trend</b>
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
<b>10. The medical device has been distributed to the following Countries</b>
<p>Within EEA, Switzerland and Turkey:</p> <p> <input type="checkbox"/> AT    <input type="checkbox"/> BE    <input type="checkbox"/> BG    <input type="checkbox"/> CH    <input type="checkbox"/> CY    <input type="checkbox"/> CZ    <input type="checkbox"/> DE    <input type="checkbox"/> DK    <input type="checkbox"/> EE    <input type="checkbox"/> ES  <input type="checkbox"/> FI    <input type="checkbox"/> FR    <input type="checkbox"/> GB    <input type="checkbox"/> GR    <input type="checkbox"/> HU    <input type="checkbox"/> IE    <input type="checkbox"/> IS    <input type="checkbox"/> IT    <input type="checkbox"/> LI    <input type="checkbox"/> LT  <input type="checkbox"/> LU    <input type="checkbox"/> LV    <input type="checkbox"/> MT    <input type="checkbox"/> NL    <input type="checkbox"/> NO    <input type="checkbox"/> PL    <input type="checkbox"/> PT    <input type="checkbox"/> RO    <input type="checkbox"/> SE    <input type="checkbox"/> SI  <input type="checkbox"/> SK    <input type="checkbox"/> TR                 </p> <p>Candidate Countries:</p> <p><input type="checkbox"/> HR</p> <p><input type="checkbox"/> All EEA, Candidate Countries, Switzerland and Turkey</p> <p>Others:</p>
<b>11. Comments</b>

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