

# **Manufacturer's Periodic Summary Report (PSR)** **Medical Devices Vigilance System (MEDDEV 2.12/1 rev 7)**

v.12/11

<b>1. Administration Information</b>	
To which NCA(s) is this report being sent?	
Date of this report	
Reference number assigned by the manufacturer	
Reference number assigned by NCA	
Type of report <input type="checkbox"/> Initial report <input type="checkbox"/> Follow up report      Follow up Number      s <input type="checkbox"/> Final report	
<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>	
Class <input type="checkbox"/> AIMD Active Implants <input type="checkbox"/> MDD Class III <input type="checkbox"/> MDD Class IIb <input type="checkbox"/> MDD Class IIa <input type="checkbox"/> MDD Class I	<input type="checkbox"/> IVD Annex II List A <input type="checkbox"/> IVD Annex II List B <input type="checkbox"/> IVD Devices for self-testing <input type="checkbox"/> IVD General
Nomenclature system (preferable GMDN)	Nomenclature code
Nomenclature text	
Notified Body (NB) ID – Number	

Model number(s) or Family Name	Catalogue number(s)
<b>7. PSR Information</b>	
PSR Type: <input type="checkbox"/> Incidents described in a Field Safety Notice  If Incidents described in a Field Safety Notice, Manufacturers reference number for FSN/FSCA	<input type="checkbox"/> Common and well documented incidents
Stage of PSR reporting based on:  <input type="checkbox"/> Observed Failure mode <input type="checkbox"/> Root cause	
Nature of problem agreed for PSR reporting	

<b>Summary period agreed:</b> <input type="checkbox"/> Every month <input type="checkbox"/> Every 2 months <input type="checkbox"/> Every 3 months <input type="checkbox"/> Every 6 months <input type="checkbox"/> Every 12 months
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<b>The figures in the table below relate to:</b>	<input type="checkbox"/> EEA + CH+ TR	<input type="checkbox"/> All PSR recipients NCA's identified in Section 1	<input type="checkbox"/> Single Member State Please name:-
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<b>Date of PSR</b>	<b>New incidents this period</b>	<b>Total number incidents via PSR</b>	<b>Total number resolved</b>	<b>Total number in progress</b>
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## 8. Manufacturer's comments / investigation results

Investigation update for this period

Initial corrective actions / preventive actions implemented by the manufacturer

Recommended actions for this period, if any

Expected date of next PSR report

## 9. Distribution

The medical device has been distributed to the following Countries

Within EEA, Switzerland and Turkey:

<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								

Candidate Countries:

☐ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:

#### 10. 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

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