

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

v.12/11

1. Administration Information	
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	
2. Information on submitter of the report	
Status of submitter <input type="checkbox"/> Manufacturer <input type="checkbox"/> Authorised Representative within EEA, Switzerland and Turkey <input type="checkbox"/> 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 <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)
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7. PSR Information

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
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Stage of PSR reporting based on: <input type="checkbox"/> Observed Failure mode <input type="checkbox"/> Root cause
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Nature of problem agreed for PSR reporting
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Summary period agreed: <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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The figures in the table below relate to:	<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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Date of PSR	New incidents this period	Total number incidents via PSR	Total number resolved	Total number in progress
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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

