# 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<br>☐ Initial report<br>☐ Follow up report Follow up Number s<br>☐ Final report |

| 2. Information on submitter of the report |
|---|
| Status of submitter<br>☐ Manufacturer<br>☐ Authorised Representative within EEA, Switzerland and Turkey<br>☐ 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<br>☐ AIMD Active Implants<br>☐ MDD Class III<br>☐ MDD Class IIb<br>☐ MDD Class IIa<br>☐ MDD Class I | ☐ IVD Annex II List A<br>☐ IVD Annex II List B<br>☐ IVD Devices for self-testing<br>☐ IVD General |
| Nomenclature system (preferable GMDN) | Nomenclature code |
| Nomenclature text | |
| Notified Body (NB) ID – Number | |

| Model number(s) or Family Name | Catalogue number(s) |
|---|---|
| | |

**7. PSR Information**

| PSR Type: | |
|---|---|
| ☐ Incidents described in a Field Safety Notice<br><br>If Incidents described in a Field Safety Notice, Manufacturers reference number for FSN/FSCA | ☐ Common and well documented incidents |
| Stage of PSR reporting based on:<br><br>☐ Observed Failure mode ☐ Root cause | |
| Nature of problem agreed for PSR reporting | |

**Summary period agreed:**

☐ Every month ☐ Every 2 months ☐ Every 3 months ☐ Every 6 months ☐ Every 12 months

| **The figures in the table below relate to:** | ☐ EEA + CH+ TR | ☐ All PSR recipients NCA's identified in Section 1 | ☐ Single Member State<br>Please name:- |
|---|---|---|---|

| **Date of PSR** | **New incidents this period** | **Total number incidents via PSR** | **Total number resolved** | **Total number in progress** |
|---|---|---|---|---|

**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:

☐ 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:

**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.

……

Name City date