10.6 ANNEX 6 - Manufacturer's PERIODIC SUMMARY REPORT FORM

Report Form
Manufacturer's Periodic Summary Report (PSR)
Medical Devices Vigilance System (MEDDEV 2.12/1 rev 8)

v. 01.13

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 ☐ Initial report ☐ Follow up report Follow up Number s ☐ Final report

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	☐ IVD Annex II List A
☐ MDD Class III	☐ IVD Annex II List B
☐ MDD Class IIb	☐ IVD Devices for self-testing
☐ MDD Class IIa	☐ IVD General
☐ MDD Class I	

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 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: ☐ 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 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.

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Name City date