

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

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

☐ 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



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



医械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



MDCPP.COM
医械云专业平台
KNOWLEDG
ECENTEROF MEDICAL
DEVICE