Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent?
Type of report ◯ Initial report ◯ Follow-up report ◯ Final report
Date of this report
Reference number assigned by the manufacturer
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable)

2 Information on submitter of the report
Status of submitter ◯ Manufacturer ◯ Authorised Representative within EEA and Switzerland ◯ Others: (identify the role)

3 Manufacturer information	new

Name	
Contact Name	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** DE - Germany

4 Authorised Representative Information

new

Name	
Contact Name	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** DE - Germany

5 National contact point information

new

National contact point name	
Name of the contact person	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** DE - Germany

6 Medical device information

new

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**
GMDN	
Nomenclature text	
Commercial name/ brand name / make	
Model number	**Catalogue number**
Serial number(s)	**Lot/batch number(s)**
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number
Accessories / associated devices (if applicable)
Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

Description and justification of the action (corrective / preventive)

Advice on actions to be taken by the distributor and the user

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

Attached please find

- ☐ Field Safety Notice (FSN) in English
- ☐ FSN in national language
- ☐ Others (please specify)

FSN Status

- ○ Draft FSN
- ○ Final FSN

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☐ 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 and Switzerland

Others:

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised 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.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail