

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 <input type="radio"/> Initial report <input type="radio"/> Follow-up report <input type="radio"/> 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 NCA Competent Authority (if applicable)

2 Information on submitter of the report
Status of submitter <input type="radio"/> Manufacturer <input type="radio"/> Authorised Representative within EEA and Switzerland <input type="radio"/> 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)

GMDN

Nomenclature code**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 <input type="checkbox"/> Field Safety Notice (FSN) in English <input type="checkbox"/> FSN in national language <input type="checkbox"/> Others (please specify)	FSN Status <input type="radio"/> Draft FSN <input type="radio"/> Final FSN																																
<p>The medical device has been distributed to the following countries:</p> <p>within the EEA and Switzerland</p> <table><tr><td><input type="checkbox"/> AT</td><td><input type="checkbox"/> BE</td><td><input type="checkbox"/> BG</td><td><input type="checkbox"/> CH</td><td><input type="checkbox"/> CY</td><td><input type="checkbox"/> CZ</td><td><input type="checkbox"/> DE</td><td><input type="checkbox"/> DK</td></tr><tr><td><input type="checkbox"/> EE</td><td><input type="checkbox"/> ES</td><td><input type="checkbox"/> FI</td><td><input type="checkbox"/> FR</td><td><input type="checkbox"/> GB</td><td><input type="checkbox"/> GR</td><td><input type="checkbox"/> HU</td><td><input type="checkbox"/> IE</td></tr><tr><td><input type="checkbox"/> IS</td><td><input type="checkbox"/> IT</td><td><input type="checkbox"/> LI</td><td><input type="checkbox"/> LT</td><td><input type="checkbox"/> LU</td><td><input type="checkbox"/> LV</td><td><input type="checkbox"/> MT</td><td><input type="checkbox"/> NL</td></tr><tr><td><input type="checkbox"/> NO</td><td><input type="checkbox"/> PL</td><td><input type="checkbox"/> PT</td><td><input type="checkbox"/> RO</td><td><input type="checkbox"/> SE</td><td><input type="checkbox"/> SI</td><td><input type="checkbox"/> SK</td><td><input type="checkbox"/> TR</td></tr></table> <p>Candidate Countries</p> <p><input type="checkbox"/> HR</p> <p><input type="checkbox"/> All EEA, candidate countries and Switzerland</p> <p>Others:</p>		<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
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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



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