

10.4 ANNEX 4 - REPORT FORM FOR FIELD SAFETY CORRECTIVE ACTION

Report Form Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

v.01.13

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 national competent authority (if applicable)	
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 National contact point information	
National contact point name	
Name of the contact person	
Address	
Postal code	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	
Commercial name/brand name/make	
Model number	Catalogue number
Serial number(s)	lot/batch number(s)
Device Manufacturing date	Expiry date
Software version number (if applicable)	
Accessories/associated device (if applicable)	
Notified body (NB) ID- number	
7 Description of 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)																																									
Attached please find ☐ Field Safety Notice (FSN) in English ☐ FSN in national language ☐ Others (please specify):	FSN Status ☐ Draft ☐ Final																																								
Time schedule for the implementation of the different actions																																									
These countries within the EEA and Switzerland and Turkey are affected by this FSCA Within EEA, Switzerland and Turkey: <table style="width: 100%; border: none;"> <tr> <td>☐ AT</td> <td>☐ BE</td> <td>☐ BG</td> <td>☐ CH</td> <td>☐ CY</td> <td>☐ CZ</td> <td>☐ DE</td> <td>☐ DK</td> <td>☐ EE</td> <td>☐ ES</td> </tr> <tr> <td>☐ FI</td> <td>☐ FR</td> <td>☐ GB</td> <td>☐ GR</td> <td>☐ HU</td> <td>☐ IE</td> <td>☐ IS</td> <td>☐ IT</td> <td>☐ LI</td> <td>☐ LT</td> </tr> <tr> <td>☐ LU</td> <td>☐ LV</td> <td>☐ MT</td> <td>☐ NL</td> <td>☐ NO</td> <td>☐ PL</td> <td>☐ PT</td> <td>☐ RO</td> <td>☐ SE</td> <td>☐ SI</td> </tr> <tr> <td>☐ SK</td> <td>☐ TR</td> <td>☐ HR</td> <td colspan="7"></td> </tr> </table> ☐ All EEA, Candidate Countries, Switzerland and Turkey Others:		☐ 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	☐ HR							
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☐ SK	☐ TR	☐ HR																																							

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

.....
Signature

Name

City

Date

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.