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
- ☐ 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	
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: ☐ 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 ☐ All EEA, Candidate Countries, Switzerland and Turkey Others:	

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.