

Report Form

Field Safety Corrective Action

Reporting Template, Version: 4, 2024
European Union Medical Devices Vigilance System

1	Administrative information		
1.1	Name(s) of National Competent Authority/ties (NCA) to which this report is sent		
1.2	Type of report ☐ Initial report ☐ Follow-up report ☐ Final report		
1.3	Date of this report		
1.4	Reference number assigned by the manufacturer		
1.5	FSCA reference number assigned by NCA		
1.6	Incidence reference number assigned by NCA		
1.7	Name of the coordinating NCA (if applicable)		
2	Information on submitter of the report		
	Status of submitter ☐ Manufacturer ☐ Authorised Representative ☐ Other: (identify the role)		
3	Manufacturer information		
3.1	Manufacturer organisation name		
3.2	Single registration number(SRN)		
3.3	Contact Name		
3.4	Address		
3.5	Postcode	3.8	City
3.6	Phone	3.9	Fax
3.7	E-mail	3.10	Country

4	Authorised Representative Information		
4.1	Authorised representative organisation name		
4.2	Single registration number(SRN)		
4.3	Contact Name		
4.4	Address		
4.5	Postcode	4.8	City
4.6	Phone	4.9	Fax
4.7	E-mail	4.10	Country
5	National contact point information		
5.1	National contact point name		
5.2	Name of the contact person		
5.3	Address		
5.4	Postcode	5.7	City
5.5	Phone	5.8	Fax
5.6	E-mail	5.9	Country

6	Medical device information	
Risk class of device when placed on the market		
6.1	MDD/AIMDD ☐ AIMDD Active implants ☐ MDD Class III ☐ MDD Class IIb ☐ MDD Class IIa ☐ MDD Class I ☐ MDD Class Is ☐ MDD Class Im ☐ MDD Class Ism	IVDD ☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD Devices for self-testing ☐ IVD General

6.2	MDR ☐ MDR Class III ☐ MDR Class IIb ☐ MDR Class IIa ☐ MDR Class I Type (Multiple choice) ☐ implantable ☐ active device ☐ intended to administer and /or remove a medicinal product ☐ sterile conditions ☐ measuring function ☐ reusable surgical instruments ☐ software ☐ systems ☐ custom-made ☐ procedure packs ☐ non-medical purpose		IVDR ☐ Class D ☐ Class C ☐ Class B ☐ Class A Type (Multiple choice) ☐ self-testing ☐ near-patient testing ☐ companion diagnostic ☐ professional testing ☐ reagent ☐ software ☐ instrument ☐ sterile conditions	
	6.3 Does the device fulfil any of the following cases: - "for this device a scientific opinion has been asked in accordance with Article 52(9) MDR or Article 52(10) MDR", - "for companion diagnostic a competent authority or European Medicines Agency (EMA) was consulted in accordance with section 5.2 of Annex IX IVDR or section 3.k of Annex X IVDR." ☐ Yes ☐ No Competent authority name or European Medicines Agency which delivered the scientific opinion or was consulted by the notified body. Name(s) of the medicinal substance(s) / product(s), tissue(s), cell(s) of human origin or their derivative(s) associated with the device.			
Unique Device Identification (UDI)				
6.4	(Master) UDI-DI/Eudamed ID		6.5	UDI production identifier
6.6	Basic UDI-DI/Eudamed-DI		6.7	Unit of use UDI-DI
Categorisation of device				
6.8	Nomenclature system (preferable EMDN)		6.9	Nomenclature code
6.10	Nomenclature text			
Description of device and commercial information				
6.11	Medical device name (brand/trade /proprietary or common name)			
6.12	Model		6.13	Catalogue/reference number
6.14	Serial number(s)		6.15	Lot/batch number(s)
6.16	Device manufacturing Date		6.17	Device expiry date

6.18	Notified Body (NB) ID-number (if applicable)	6.19	Software version number (if applicable)
6.20	Accessories / Associated Devices (if applicable)		

7	Description of the FSCA						
7.1	Background information and reason for the FSCA						
7.2	Is there suspicion or confirmation of a relationship between the FSCA and the medicinal substance(s) / product(s), tissue (s), cell(s) of human origin or their derivative(s) associated with the device? ☐ Yes ☐ No						
IMDRF codes							
7.3	IMDRF 'Medical device problem codes' (Annex A)	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
		Code	Code	Code	Code	Code	Code
7.4	IMDRF Cause investigation: Investigation findings (Annex C)	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
		Code	Code	Code	Code	Code	Code
7.5	IMDRF Cause investigation: Investigation conclusion (Annex D)	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
		Code	Code	Code	Code	Code	Code
7.6	Description and justification of the corrective / preventive action						
7.7	Advice on actions to be taken by the distributor and the user						
7.8	Progress of FSCA , together with reconciliation data (mandatory for a Final FSCA)						
7.9	Time schedule for the implementation of the different actions						

7.10	Attached please find:		FSN Status																																						
	☐ Field Safety Notice (FSN) in English ☐ FSN in national language ☐ Others (please specify)		☐ Draft FSN ☐ Final FSN																																						
7.11	Market distribution of device (region/country)																																								
	☐ All EEA, Turkey and Northern Ireland The code XI is used for Northern Ireland <table border="0" style="width: 100%;"> <tr> <td>☐ AT</td> <td>☐ DE</td> <td>☐ FR</td> <td>☐ IS</td> <td>☐ LV</td> <td>☐ RO</td> <td rowspan="5">Others:</td> </tr> <tr> <td>☐ BE</td> <td>☐ DK</td> <td>☐ GR</td> <td>☐ IT</td> <td>☐ MT</td> <td>☐ SE</td> </tr> <tr> <td>☐ BG</td> <td>☐ EE</td> <td>☐ HR</td> <td>☐ LI</td> <td>☐ NL</td> <td>☐ SI</td> </tr> <tr> <td>☐ CY</td> <td>☐ ES</td> <td>☐ HU</td> <td>☐ LT</td> <td>☐ NO</td> <td>☐ SK</td> </tr> <tr> <td>☐ CZ</td> <td>☐ FI</td> <td>☐ IE</td> <td>☐ LU</td> <td>☐ PL</td> <td>☐ TR</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td>☐ PT</td> <td>☐ XI</td> <td></td> </tr> </table>				☐ AT	☐ DE	☐ FR	☐ IS	☐ LV	☐ RO	Others:	☐ BE	☐ DK	☐ GR	☐ IT	☐ MT	☐ SE	☐ BG	☐ EE	☐ HR	☐ LI	☐ NL	☐ SI	☐ CY	☐ ES	☐ HU	☐ LT	☐ NO	☐ SK	☐ CZ	☐ FI	☐ IE	☐ LU	☐ PL	☐ TR					☐ PT	☐ XI
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8	General 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.

check the form

Please note

- you can sign the document only after checking the form and completing all mandatory fields
- after signing the document it is not possible to modify the data

Signature

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