Manufacturer's Trend Report Form (MTR)

Reporting Template Version 1.0

European Union Medical Devices Vigilance System

Section 1: Administrative information

1.1 Corresponding national competent authority(ies) NCA(s)

a Countries in which the incidents, expected undesirable side effects (MD), expected erroneous results (IVD) occurred

AT		BE		BG		CY		CZ		DE	
DK		EE		ES		FI		FR		GR	
HR		HU		IE		IS		IT		LI	
LT		LU		LV		MT		NL		NO	
PL		PT		RO		SE		SI		SK	
TR		XI									
	All EEA, Turkey and Northern Ireland										

Other countries (outside EEA+TR+XI):

b To which NCA(s) is this report being sent?

EUDAMED number of NCAs

c NCA of the country where the manufacturer or authorised representative is located

d EUDAMED Reference number for this MTR

1.2 Date type and classification of Trend Report

a Date of submission

YYYY MM DD

b Date when the trend was identified

YYYY MM DD

c Time period of trend analysis

YYYY MM DD to YYYY MM DD

d Regulatory type(s) of device(s)

MD (MDR, MDD, AIMDD) or

	IVD (IVDR, IVDD)	
e	Basis for the report - type ☐ Incident ☐ Expected undesirable side effect (MD only) ☐ Expected erroneous results (IVD only)	Basis for the report – what increased ☐ Frequency ☐ Severity
f	Type of report ☐ Initial ☐ Follow up ☐ Combined initial and final ☐ Final	
g	In case of initial and follow-up reports, please indicate the expected date of the next report YYYY MM DD	
h	The trend was detected within a post market clinical follow up (PMCF)/ post market performance follow up (PMPF) investigation? Yes/No	
i	If the trend was detected within a PMCF/PMPF investigation; please provide the Eudamed ID of that PMCF/PMPF investigation	

1.3 Submitter information

1.3.1 Submitter of the report

a	☐ Manufacturer **(MF)** ☐ Authorised representative **(AR)** ☐ MF or AR Sub-contractor
b	Manufacturer's reference number for this MTR

1.3.2 Manufacturer information

a	Manufacturer organisation name		
b	Actor ID/Single Registration number (SRN)		
c	Contact's first name	**d**	Contact's last name
e	Email	**f**	Phone
g	Country		
h	Street	**i**	Street number
j	Address complement	**k**	PO Box
l	City name	**m**	Postal code

1.3.3 Authorised representative information

a	Authorised representative organisation name		
b	Actor ID/Single Registration Number		
c	Contact's first name	d	Contact's last name
e	Email	f	Phone
g	Country		
h	Street	i	Street number
j	Address complement	k	PO Box
l	City name	m	Postal code
1.3.4	**Submitter's details if subcontractor of manufacturer or authorised representative**		
a	Registered commercial name of company		
b	Contact's first name	c	Contact's last name
d	Email	e	Phone
f	Country		
g	Street	h	Street number
i	Address complement	j	PO Box
k	City name	l	Postal code

Section 2: Device information

2.1	**Type of device scope**
a	☐ Category / Group / Type(s) from European Medical device nomenclature (EMDN) (not for IVD, neither for old devices) ☐ Basic UDI-DI(s)/Eudamed DI(s) ☐ (Master) UDI-DI(s)/ Eudamed ID(s) / Device name(s) and reference/ catalogue number ☐ UDI-DI and UDI-PI(s)/ Eudamed ID/Device name and Lot/Batch number(s)
2.2	**Device(s) scope Identification**
a	EMDN code(s) Nomenclature text for each code (Display only)

b	Basic UDI-DI(s)/ Eudamed DI(s) Issuing entity List all applicable *For each Basic UDI-DI/EUDAMED DI at least the following will be additionally displayed from UDI/Device data:* Applicable legislation Risk class Name and/or Model
c	UDI-DI(s)/EUDAMED ID(s) /Device name(s) Issuing entity (if applicable) *List all applicable* *For each UDI-DI/EUDAMED ID/Device at least the following will be additionally displayed from UDI/Device data (for Regulation and Legacy devices) or to be provided (for Old devices):* Applicable legislation Basic UDI-DI/EUDAMED DI (only for Regulation and Legacy devices) Risk class EMDN code(s) and title(s) (Trade name(s), Catalogue/Ref number(s)
d	UDI-DI/EUDAMED ID/Device name Issuing entity (if applicable) UDI-PI(s)/Lot/Batch number(s) *List all applicable* *For the UDI-DI/EUDAMED ID/Device at least the following will be additionally displayed from UDI/Device data (for Regulation and Legacy devices) or to be provided (for Old devices):* Applicable legislation Basic UDI-DI/EUDAMED DI (only for Regulation and Legacy devices) Risk class EMDN code(s) and title(s) Trade name, Catalogue/Ref number

2.3 Risk class of device(s) when placed on market

a	**MDD/AIMDD** ☐ active implant ☐ class III ☐ class IIb ☐ class IIa ☐ class I ☐ class Is ☐ class Im ☐ custom made	**IVDD** ☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD devices for self-testing ☐ IVD general

b	**MDR** ☐ class III ☐ class IIb ☐ class IIa ☐ class I	Type (Multiple choice) ☐ implantable ☐ active device intended to administer and/or remove a medicinal product ☐ sterile conditions ☐ measuring function	**IVDR** ☐ class D ☐ class C ☐ class B ☐ class A	Type (Multiple choice) ☐ self-testing ☐ near-patient testing ☐ companion diagnostic ☐ Reagent ☐ software ☐ instrument ☐ sterile conditions

		☐ reusable surgical instruments ☐ software ☐ system ☐ procedure packs ☐ custom-made ☐ non-medical purpose		☐ professional testing

2.4	**Notified Body Information**
a	Notified body (NB) ID number(s) (if applicable)

Section 3: Description of Trend

3.1	Background information on the trend, including probability of problem arising and the predicted risk to patient, users or other persons.
3.2	**Coded information on trend**
3.2.1	**Medical device problem information**
a	IMDRF Medical device problem codes (Annex A) or in-house codes

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code	Code	Code	Code	Code	Code

In-house codes	Choice 1 (most relevant)	Choice 2	Choice 3
Code			
Term			

3.2.2	**Health effect**
a	IMDRF 'Clinical signs and symptoms, or conditions'(Annex E) and 'Health Impact' (Annex F) terms and codes or in-house /MedDRA codes

	Choice 1 (most relevant)	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Clinical signs and symptoms or conditions codes' (Annex E)	Code	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code	Code	Code	Code	Code	Code

In-house/MedDRA codes	Choice 1 (most relevant)	Choice 2	Choice 3

	Code				
	Term				
3.3	**Root Cause Analysis**				
a	Summary of the root cause analysis				
3.4	**Actions to be taken or implemented to reduce the risks for the users/patients**				
a	Corrective actions information and justification if the corrective or preventive actions has not been taken				
3.5	**General Comments**				
3.6	**Upload the Trend Report document (pdf)**				
a	Trend report document to upload (pdf)				