

# Manufacturer's Trend Report Form (MTR)

Reporting Template Version 1.0

European Union Medical Devices Vigilance System

## Section 1: Administrative information

<b>1.1</b>	<b>Corresponding national competent authority(ies) NCA(s)</b>																																																																																																
<b>a</b>	Countries in which the incidents, expected undesirable side effects (MD), expected erroneous results (IVD) occurred																																																																																																
	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td>AT</td><td></td><td>BE</td><td></td><td>BG</td><td></td><td>CY</td><td></td><td>CZ</td><td></td><td>DE</td><td></td> </tr> <tr> <td>DK</td><td></td><td>EE</td><td></td><td>ES</td><td></td><td>FI</td><td></td><td>FR</td><td></td><td>GR</td><td></td> </tr> <tr> <td>HR</td><td></td><td>HU</td><td></td><td>IE</td><td></td><td>IS</td><td></td><td>IT</td><td></td><td>LI</td><td></td> </tr> <tr> <td>LT</td><td></td><td>LU</td><td></td><td>LV</td><td></td><td>MT</td><td></td><td>NL</td><td></td><td>NO</td><td></td> </tr> <tr> <td>PL</td><td></td><td>PT</td><td></td><td>RO</td><td></td><td>SE</td><td></td><td>SI</td><td></td><td>SK</td><td></td> </tr> <tr> <td>TR</td><td></td><td>XI</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td colspan="12" style="text-align: center;">All EEA, Turkey and Northern Ireland</td> </tr> <tr> <td colspan="12" style="text-align: center;">Other countries (outside EEA+TR+XI):</td> </tr> </table>	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):											
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<b>b</b>	To which NCA(s) is this report being sent?  EUDAMED number of (NCA)s (if available)																																																																																																
<b>c</b>	NCA of the country where the manufacturer or authorised representative is located																																																																																																
<b>d</b>	Reference number assigned by NCA(s) / EUDAMED ID for this <b>Trend report (MTR)</b>																																																																																																
<b>1.2</b>	<b>Date, type, and classification of Trend Report</b>																																																																																																
<b>a</b>	Date of report submission in format YYYY MM DD																																																																																																
<b>b</b>	Date when the trend was identified in format YYYY MM DD																																																																																																
<b>c</b>	Time period of trend analysis in format YYYY MM DD to YYYY MM DD																																																																																																
<b>d</b>	Regulatory type(s) of device(s) MD: <input type="checkbox"/> MDR <input type="checkbox"/> MDD <input type="checkbox"/> AIMDD																																																																																																

	or IVD: <input type="checkbox"/> IVDR, <input type="checkbox"/> IVDD		
<b>e</b>	Basis for the report – <u>type</u>  <input type="checkbox"/> Incident <input type="checkbox"/> Expected undesirable side effect (MD only) <input type="checkbox"/> Expected erroneous results (IVD only)		Basis for the report – <u>what has increased</u>  <input type="checkbox"/> Frequency <input type="checkbox"/> Severity
<b>f</b>	Type of report <input type="checkbox"/> Initial <input type="checkbox"/> Follow up <input type="checkbox"/> Combined initial and final <input type="checkbox"/> Final		
<b>g</b>	In case of initial and follow-up reports, please indicate the expected date of the next report in format YYYY MM DD		
<b>h</b>	The trend was identified within a post market clinical follow up PMCF/post market performance follow-up PMPF investigation? Yes/No		
<b>i</b>	If the trend was identified within a PMCF/PMPF investigation please provide the NCA / Eudamed ID of that PMCF/PMPF investigation		
<b>1.3 Submitter information</b>			
<b>1.3.1 Submitter of the report</b>			
<b>a</b>	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Authorised representative <input type="checkbox"/> Other, please specify		
<b>b</b>	Manufacturer's reference number for this Trend report		
<b>1.3.2 Manufacturer information</b>			
<b>a</b>	Manufacturer organisation name		
<b>b</b>	Actor ID/Single Registration Number(SRN)		
<b>c</b>	Contact's first name	<b>d</b>	Contact's last name
<b>e</b>	Email	<b>f</b>	Phone
<b>g</b>	Country		
<b>h</b>	Street	<b>i</b>	Street number
<b>j</b>	Address complement	<b>k</b>	PO Box
<b>l</b>	City name	<b>m</b>	Postal code

<b>1.3.3 Authorised representative information</b>			
<b>a</b>	Authorised representative organisation name		
<b>b</b>	Actor ID/Single Registration Number		
<b>c</b>	Contact's first name	<b>d</b>	Contact's last name
<b>e</b>	Email	<b>f</b>	Phone
<b>g</b>	Country		
<b>h</b>	Street	<b>i</b>	Street number
<b>j</b>	Address complement	<b>k</b>	PO Box
<b>l</b>	City name	<b>m</b>	Postal code

<b>1.3.4 Submitter's details if not also manufacturer or authorised representative</b>			
<b>a</b>	Registered commercial name of company		
<b>b</b>	Contact's first name	<b>c</b>	Contact's last name
<b>d</b>	Email	<b>e</b>	Phone
<b>f</b>	Country		
<b>g</b>	Street	<b>h</b>	Street number
<b>i</b>	Address complement	<b>j</b>	PO Box
<b>k</b>	City name	<b>l</b>	Postal code

## Section 2: Device information

<b>2.1 Type of device scope</b>	
<b>a</b>	<input type="checkbox"/> Category / Group / Type(s) from European Medical Device Nomenclature (EMDN) (not for IVD, neither for old devices) <input type="checkbox"/> Basic UDI-DI(s)/Eudamed DI(s) <input type="checkbox"/> (Master) UDI-DI(s)/ Eudamed ID(s) / Device name(s) and reference/ catalogue number <input type="checkbox"/> UDI-DI and UDI-PI(s)/ Eudamed ID/Device name and Lot/Batch number(s)
<b>2.2 Device(s) scope Identification</b>	

a	EMDN code(s) Nomenclature text for each code (Display only)			
b	Basic UDI-DI(s)/ Eudamed DI(s) Issuing entity <i>List all applicable</i> <i>For each Basic UDI-DI/EUDAMED DI at least the following will be additionally displayed from UDI/Device data:</i> Applicable legislation Risk class Name and/or Model			
c	(Master) UDI-DI(s)/EUDAMED ID(s) /Device name(s) Issuing entity (if applicable) <i>List all applicable</i> <i>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):</i> 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) <i>List all applicable</i> <i>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):</i> 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			
<b>2.3 Risk class of device(s) when placed on market</b>				
a	<b><u>MDD/AIMDD</u></b> <input type="checkbox"/> active implant <input type="checkbox"/> class III <input type="checkbox"/> class IIb <input type="checkbox"/> class IIa <input type="checkbox"/> class I <input type="checkbox"/> class Is <input type="checkbox"/> class Im <input type="checkbox"/> class Ism <input type="checkbox"/> custom made		<b><u>IVDD</u></b> <input type="checkbox"/> IVD Annex II List A <input type="checkbox"/> IVD Annex II List B <input type="checkbox"/> IVD devices for self-testing <input type="checkbox"/> IVD general	
b	<b><u>MDR</u></b> <input type="checkbox"/> class III <input type="checkbox"/> class IIb <input type="checkbox"/> class IIa <input type="checkbox"/> class I	<b><u>Type (Multiple choice)</u></b> <input type="checkbox"/> implantable <input type="checkbox"/> active device intended to administer and/or remove a medicinal product	<b><u>IVDR</u></b> <input type="checkbox"/> class D <input type="checkbox"/> class C <input type="checkbox"/> class B <input type="checkbox"/> class A	<b><u>Type (Multiple choice)</u></b> <input type="checkbox"/> self-testing <input type="checkbox"/> near-patient testing <input type="checkbox"/> companion diagnostic <input type="checkbox"/> professional testing

	<input type="checkbox"/> sterile conditions <input type="checkbox"/> measuring function <input type="checkbox"/> reusable surgical instruments <input type="checkbox"/> software <input type="checkbox"/> systems <input type="checkbox"/> custom-made <input type="checkbox"/> procedure packs <input type="checkbox"/> non-medical purpose		<input type="checkbox"/> Reagent <input type="checkbox"/> software <input type="checkbox"/> instrument <input type="checkbox"/> sterile conditions
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## 2.4 Notified Body Information

<b>a</b>	Notified body (NB) ID number(s) (if applicable)
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## Section 3: Description of Trend

<b>3.1</b>	Background information on the trend, including probability of problem arising and the predicted risk to patient, users or other persons.
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### 3.2 Coded information on trend

#### 3.2.1 Medical device problem information

<b>a</b>	IMDRF Medical device problem codes (Annex A)						
	Choice 1 <i>(most relevant)</i>	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	
	IMDRF 'Medical device problem codes'	Code	Code	Code	Code	Code	Code
	If exceptionally no relevant IMDRF code is available or specific enough, then provide additional information below (no code but a description)						

#### 3.2.2 Health effect

<b>a</b>	IMDRF "Health effects" terms and codes 'Clinical signs and symptoms and conditions' (Annex E) and 'Health Impact' (Annex F) terms						
	Choice 1 <i>(most relevant)</i>	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	
	IMDRF 'Clinical signs, symptoms and conditions codes' (Annex E)	Code	Code	Code	Code	Code	Code
	IMDRF 'Health impact' codes (Annex F)	Code	Code	Code	Code	Code	Code
	If exceptionally no relevant IMDRF code is available or specific enough, then provide additional information below:						

<b>3.3</b>	<b>Root Cause Analysis</b>
a	Summary of the root cause analysis
<b>3.4</b>	<b>Actions to be taken or implemented to reduce the risks for the users/patients</b>
a	Information about corrective or preventive actions or any other measure
<b>3.5</b>	<b>General Comments</b>
<b>3.6</b>	<b>Upload the Trend Report document (pdf)</b>
a	Trend report document to upload (.pdf)

*Submission of this report does not 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. I affirm that the information given above is correct to the best of my knowledge.*