**MDCG 2022-21 – Periodic Safety Update Reports (PSUR)**

(Provided by Casus in word format. This is an exact transposition from the PDF version of MDCG 2022-21)

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**ANNEX V: PSUR Web Form for Manufacturer**

* The PSUR Web form for manufacturer contains all the relevant administrative data necessary for the registration of the PSUR in EUDAMED: certain fields are automatically populated by EUDAMED e.g. Notified Body, Manufacturer, Single Registration Number (SRN) while other data need to be filled up by the manufacturer via EUDAMED Web interface.
* When EUDAMED becomes fully functional, the manufacturer should upload the PSUR in PDF format into EUDAMED for MDR class III devices or implantable devices and provide the information\* of the PSUR Web form directly through the EUDAMED Web interface.
* The manufacturer should create a PSUR reference number which should remain the same for the PSUR updates. In case of grouping of devices within one PSUR, the PSUR reference number relates to the leading device.
* When registering a PSUR in EUDAMED, the manufacturer should capture the Basic UDI-DIs of all the Class III or implantable devices belonging to the group via the web interface.
* For PSURs which are not required in EUDAMED, the PSUR Web form is not applicable. Instead, the manufacturer should fill in the information required in the PSUR cover page (see Annex I of this guidance).

**PSUR Web Form\* for Manufacturer**

|  |  |
| --- | --- |
| 1 | Manufacturer information  |
| A | Manufacturer SRN  |
| B | Manufacturer organisation name  |
| 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  |

|  |  |
| --- | --- |
| 2 | Authorised representative information |
| A | SRN  |
| B | Authorised representative organisation name  |
| 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  |

|  |  |
| --- | --- |
| 3 | Corresponding Competent Authority  |
| A | Name of National Competent Authority (NCA)  |
| B | EUDAMED number of NCA  |

|  |  |
| --- | --- |
| 4 | Notified Body  |
| A | NB organisation name and number  |
| B | Email |

|  |  |
| --- | --- |
| 5 | Medical Device Information  |
| A | Leading device Basic UDI-DI  |
| B | Other Basic UDI-DI(s) / Eudamed DI(s)-  |
| C | For each Basic UDI-DI / Eudamed DI, NB number and Certificate ID(s) |

|  |  |
| --- | --- |
| 6 | PSUR Submission in Eudamed  |
| A | Date of submissionYYYY MM DD  | Scheduled date YYYY MM DD  | Timeliness Days  |
| B | PSUR Reference number |
| C | Data collection periodYYYY MM DD - YYYY MM DD |
| D | Version Number  |

|  |  |
| --- | --- |
| 7 | Upload the PSUR document  |

\*Only the fields and content of the PSUR Web form need to be considered and not its structure which may be different in the EUDAMED web interface.