ANNEX I: TEMPLATE FOR THE PSUR REPORT and PSUR Follow-up REPORT

a) **Executive summary**

- Describe the main results of the current PSUR and provide background information so that the PSUR "stands alone".
- Executive summary should provide a clear and bold statement declaring whether the benefit risk ratio has been negatively impacted based on the information reported within the current PSUR. This statement should be added after the conclusions of the PSUR have been completed.

b) **Description of the devices covered by the PSUR and their intended uses**

- Provide a tradename or tradenames and nomenclature terms of the devices covered by the PSUR.
- In cases where the PSUR covers multiple devices provide the number of devices included in the current PSUR and explain whether all grouped devices are master devices or master device and its assessor(s).
- Provide a brief description of the device(s) intended use and the patient groups the device is intended. Describe the expected use of the device in different patient groups, in different sizes and variants when applicable.
- Provide information related to the contraindications and warnings.

c) **Justification of the grouping of devices if applicable**

- In cases where the PSUR includes more than one Basic UDI-DI or model of the MDD, AIMDD devices or custom-made devices describe the justification to group the devices in one PSUR.
- The justification could be based on the benefits to report multiple devices in one PSUR or alternatively weaknesses to report each device in separate PSURs.
- In any case, take into account that the PSUR must remain comprehensible.

d) **Post Market data and their evaluation**

General information related to the data presentation and evaluation is describe in Annex

II and examples of used tables in Annex III.

e) **Estimated population and usage frequency of devices and volume of sales**

- **Characteristics of the population using the device(s)**
    - Describe the observed usage of the device in different patient populations in comparison to the expected usage and identify the possible over-represented or under-represented patient groups.
    - Regarding implants describe the size and nature of the patient population with the implanted medical device and proportion of the patient group using the implant in comparison to the population.
    - Consider the off-label use as a whole and in specific patient or disease groups.
    - Describe the possible changes in patient groups using the device during the last four years on a year to year basis. Evaluate the effect of the detected changes to findings obtained previously and in the current PSUR.
    - Estimate the generalizability of the results.

- **Volume of sales**
    - Provide an accurate information of the number of devices sold and the possible changes on it. The data should be presented by year to year.
    - Provide also further information on the volume of sales in respect to the various sizes, models and system components of the device.
        - Total number of devices placed on the market or put into service
        - Number of implanted devices
        - Number of units distributed within a defined period
        - Devices on the market, based on: Devices placed on the market or put into service
        - Active installed base
        - Other (describe)

f) **Presentation of the data and their evaluation**

- **Post market clinical follow-up studies and evaluation**
    - Firstly provide a list of the studies including following data: name or code of the study, completed or ongoing study, type of study, number of study sites, number of enrolled and target patients, adverse event rate and number of deaths shall be provided.
    - Secondly provide a list of adverse events, both serious and non-serious, by IMDRF device problem code. The list should be in descending order so that the first entry is the most common device problem type occurred in EU+TR+CH.
    - Describe the primary and secondary endpoints or the pre-identified safety and health threshold by study and for completed studies also the extent of how the objectives have been achieved.
    - The data evaluation should include the comparison of findings from different studies on each other and when not in line give a justification.

- **Possible change of state of art**
  To be developed

- **Vigilance data including trending /signals and evaluation**
    - The serious incidents and non-serious incidents should be reported saparatly
    - The data relating to serious incidents should contain all occurred serious incidents.
    - The data related to the non-serious incidents should include incidents categorised a as trend report and top ten non-serious incidents not included in a trend report.
    - Firstly provide a list of serious and non-serious incidents by IMDRF device problem code by year to year. Organize the list in descending order so that the first one is the most common device problem type occurred in EU+TR+CH within current reporting period.
    - Secondly provide a list of the health impacts by IMDRF health impact code. Use the 4-year summary data and split the data by the device problems (proportion) caused the health impact. Organize the list in descending order so that the first entry is the most common health impact occurred in EU+TR+CH within current reporting period.
    - Thirdly provide a list of investigation findings by IMDRF investigation finding code by year to year. Organize the list in descending order so that the first entry is the most common investigation finding occurred in EU+TR+CH within current reporting period.

- Provide a list of new signals detected in current PSUR, previously detected signals and their status (switch to risk, eliminated, still monitoring) and re-opened signals and reason for re-opening. Use the 4-year summary data.
- For each signal, evaluate the significance of it and describe plans for further evaluation of it and if no action is planned justify it.

- **Preventive and Corrective Actions (Article 83.4)**
  - Provide a list of preventive and corrective actions including following information: the type of action, name of the action, method to detect the requirement to release a CAPA, the root cause, actions taken, proportion of CAPA's that indicated a FSCA and results of the actions.
  - The analysis should identify whether there are deviations from the defined actions, the identified actions should be listed, and the deviation should be justified.
  - In cases where identical CAPAs are repeated provide an explanation.

- **Preventive and corrective actions for safety reasons and evaluation (Article 87)**
  - FSCAs will be reported according to the current FSCA forms until Eudamed is functional. When Eudamed is functional and the data collection related to the FSCA reports is updated this part of PSUR will be also updated.
  - Provide a list of FSCAs performed including following information: manufacturer's reference number, the date of initiation, a brief description of the reason for action, status at the time of the PSUR (i.e. initial, follow-up, final) and information whether a Field Safety Notice has been issued.
  - The analysis should identify whether there are deviations from the defined actions, when identified those actions should be listed and justify the deviation.
  - When identical FSCAs are performed repeatedly they should be justified.
  - Clarification for the prolonged duration of the corrective actions shall be provided.

- **Post market surveillance data (safety and performance) and evaluation**
  - Provide a list of the other data sources collected on the basis of the PMSP. Use that part of the data, which is related to the device safety and performance, and enable the comparison to other devices with same intended use.
  - Systematic Literature Research
    - Provide a list of completed literature searches including following information: name of the literature search, indication for the literature search, search terms, used data sources, proportion of the accepted publications, number of patients and findings.
  - Register data
    - Provide a list of all registers including following information: the name or registry reference, type of registry (Prospective or Retrospective data collection), start date of registry, most recent enrolment numbers/recruitment target (With justification to delays in recruitment), number and geographical location of registry sites including the addition or exclusion of any sites.
    - Provide a list of findings in comparison to the devices with same intended use and justify the possible differences.

        - For the publicly published register provide its location.

- **Other data sources**
    - The other used data sources could be for example real-world data from electronic health records, digital health-monitoring, complaints, and other feedback from health care professionals.

g) **Summary of the findings**

- Provide an overview of the data; its coverage, quality, possible deficiencies and bias.
- Give a resolution that is based on all used datasets and evaluate whether the findings obtained are consistent with the finding reported in the previous PSURs.
- Provide a list of the possibly detected deviations, positive or negative and duly justify each.
- Highlight the strengths and limitations of the data and analysis used.
- Compare the findings to the other devices with same intended use and state of art and justify the possible differences in safety and performance of the device.

h) Assessment of the benefit/risk profile by manufacturer

- Baseline safety and performance information
    - Provide a summary that demonstrates the achieved safety and performance of the device recorded prior to the current PSUR and outlined in the device risk assessment documentation.
    - The summary should also include the baseline benefit information.
    - The information should relate to the intended use(s) of the device.

- Update on characterization of risks
    - Provide a list of the observed and potential new risks by patient groups, device sizes, accessories used and region.
    - Of the detected new risks, give an estimate of the seriousness, potential impact and duration of each.
    - Provide also a list of the known risks which prevalence or seriousness has increased.
    - Evaluate the clinical significance of the new detected risks and changed risks.

- Risk reduction actions and their effectiveness
    - In cases where there are new risks identified, and the prevalence or seriousness of a known risk has increased provide a list of the risk reduction activities performed.
    - The effectiveness of risk reduction activities should be evaluated and where actions have not be taken provide justification.
    - Summarized the information by region, patient groups and device sizes or models if applicable and relevant.

- Update of characterization of benefits
    - Provide a list of the new detected benefits and benefits not gained by patient groups, device sizes, accessories and region.
    - Regarding the detected new benefits and benefits not gained, evaluate the clinical significance and duration of them.
    - Describe the effect of the benefits not gained to the acceptability of the usages of the device.

- Summarized the information by region, patient groups and device sizes or models if applicable and relevant.

- Update to benefit-risk profile
  - Provide a summary of the benefit risk update and justify the actions you have or not have taken.
  - Compare the benefit risk ratio of the device to the other devices with same intended use.

i) Conclusions of the PSUR report

- Provide a statement declaring whether the benefit risk ratio has been negatively impacted based on the information reported within the current PSUR and add the resolution in section Executive Summary
- Identify specific points that should be considered in the next PSUR.

j) The effects of the results on the PMS plan

- Describe how the current PSUR will affect to the further PMS
- Provide a list of the updated documents and describe the updated content.
- Describe the essential changes on the PMS plan.

ANNEX II: General information related to the data reporting and their evaluation

A. How Data should be reported

- Each dataset collected within PMS Plan should be presented and analysed individually and finally provide a summary of the all used datasets highlighting the strengths and weaknesses of the used data.
- Each individual data should be split by Basic UDI-DI or model of the device if the Basic UDI-DI does not exist.
- The data should be split also by region when applicable. The used region is EU, CH, TR and worldwide. Worldwide data should not include data from EU, CH and TR.
- Each PSUR contains data gathered over the last four years.
- Depending on the detail, the data is used as a 4-year summary data or a yearly data.
- Data reported by year to year:
    - Class III and Class IIb: Reporting Day+ preceding 12 months (N); N – 12 months (N2); N2-12 months (N3); N3-12 months (N4)
    - Class IIa: Reporting Day+ preceding 24 months (N); N – 24 months (N2)
- Report the data by the International Medical Device Regulators Forum (IMDRF) codes when the content of the data facilitates it.
    - Level 2 terms are satisfactory to enable the grouping of cases.
    - When the level 2 terms are not available use the level 1 terms.
        - The used codes are device problem code (Annex A)
        - Health impact code (Annex F)
        - Investigation finding code (Annex C)

B. How data should be evaluated

- Findings from all used datasets should be evaluated against each other with consideration and reflect the possible conflicting results.
- Evaluate the generalizability of the results in viewpoint of the different patient populations, size and model of the device or device combination.
- When applicable evaluate the findings in relation to the state of the art.
- Evaluate the data in relation to the predefined thresholds concerning known side effects and benefits intended to gain.
- Identify the possible unknown signals, positive or negative.
- The short-term findings should be evaluated against the long-term findings.
- Where applicable use the IMDRF adverse event codes in the analysis.
- Identify factors that supports or refutes previously identified safety and performance concerns as well as evidence relating to new safety signals and previously unknown benefits.

- Whether the device is used as a combination of devices the analysis should identify the role of the target device in comparison to other devices or accessories. Compare the performance and safety of the device to other devices with the same intended use.
- For detecting signals describe overall principles and methodology including trigger levels and their justifications and the method used to detect signals.

ANNEX III: TEMPLATES FOR REPORTING OF DATA

Table 1. Worldwide volumes of sales (reported by EU+CH+TR and World)

Device name					
	Total Number of devices in expected lifetime	Reporting Day+ preceding 12 months (N)	N – 12 months (N2)	N2-12 months (N3)	N3-12 months (N4)
EU+CH+TR					
World					

Table 2. Size and characteristic of population

Estimated size of the patient population	Estimated number of patients using the device	Proportion of elderly (%)	Proportion of paediatric patients (%)	Proportion of specify (%)	Proportion of specify (%)

Table 3. List of the PMCF studies

Name or code of the study	Completed (Yes/No)	Type of the study	Number of study sites	N of patients enrolled and the target number		N of serious incidents	Serious incident rate (%)	N of deaths

Table 4. Serious incidents by the IMDRF codes and EU+CH+TR and World

Device name						
Problem code	Health Effect	Investigation Finding	N of serious incidents during PSUR reporting period	Number of serious incidents by Region		Incident rate (%)
				WW		
				EU+CH+TR		
				WW		
				EU+CH+TR		

Table 5. Serious incidents over preceding XX years for lower volume devices

Device name						
Problem code	Health Effect	Investigation Finding	N of serious incidents during xxx years	Number of serious incidents by Region		Incident rate (%)
				WW		
				EU+CH+TR		
				WW		
				EU+CH+TR		

Table 6. Incidents during PSUR reporting period by device problem code and region

Device Problem Code	Health Effect	Included in trend report (Y/N)	N of incidents during PSUR reporting period	Number of incidents by Region		Incident Rate (%)
				WW		
				EU+CH+TR		
				WW		
				EU+CH+TR		

Table 7. Vigilance data by Investigation finding code and region

Investigation finding code	Cumulative Serious Incident rate (%)		Number of Serious Incidents PSUR Reporting period (N)		N – 12 months (N2)		N2-12 months (N3)		N3-12 months (N4)	
	WW		WW		WW		WW		WW	
	EU+CH +TR		EU+CH +TR		EU+CH +TR		EU+CH +TR		EU+CH +TR	
	WW		WW		WW		WW		WW	
	EU+CH +TR		EU+CH +TR		EU+CH +TR		EU+CH +TR		EU+CH +TR	

Table 8. FSCA during the PSUR reporting period and the status of the FSCA

Device name					
Type of action	Starting Date	Staus of the FSCA	Mnfr. Reference number	Rationale and description of action taken	Impacted regions

Table 9. Actions taken for safety reasons outside the FSCA

Type of action	Starting Date	Staus of the action	Rationale and description of action taken	Impacted regions

Table 10. Other data sources

Type of data	A relevant specifier (N of complaints, devices)

Table 11. Observed risks and benefits

Risk	Previously known (Y/N)	Prevalence in PSUR reporting period	Prevalence in PSUR Period	Threshold	Effect to Benefit risk ratio (Y/N)
Benefits					

Table 12. The method to verify the gained benefits and the gained benefits

Study	Method	Observed benefit	Threshold		Difference

Table 13$_1$. Annual reporting of the phenomena

BASIC UDI-DI/Device name or model					
Name of the reported item		Reporting Day+ preceding 12 months (N)	N – 12 months (N2)	N2-12 months (N3)	N3-12 months (N4)
EU+CH+TR					
WW					
EU+CH+TR					
WW					

*The name of the column could vary (number of device sold; total number of implanted; prevalence of serious incidents/non-serious incidents/adverse events by IMDRF device problem code; prevalence of investigation findings by IMDRF investigation findings code.

Table 14$_2$. Reporting 4-year summary data

BASIC UDI-DI/Device name or model					
Name of the reported item*		Proportion of reported phenomena %	Proportion of reported phenomena %	Proportion of reported phenomena %	Proportion of reported phenomena %
EU+CH+TR					
WW					
EU+CH+TR					
WW					

*The name of the column could vary (estimated number of patients using the device+ proportion on different patient groups; IMDRF Health impact code + proportion of the device problem causing the health effect).

Annex IV: TERMINOLOGY

Benefit-risk determination: the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer. MDR Article 2(24).

Equivalent medical devices: Devices in which clinical, technical and biological characteristics defined in Annex XIV part A shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. MDR Annex XIV part A, section 3.

Making available in the market: means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. MDR Article 2(27)

OLD DEVICES; MDD devices, not placed on the market after 26 May 2021)

PERIODIC SAFETY UPDATE REPORT (PSUR): Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. MDR Article 86. The PSUR (REPORT) is composed of two elements: the PSUR FORM and the PSUR DOCUMENT.

PSUR FORM: Template that contains all the relevant administrative data requested in the PSUR. This FORM details information regarding the medical device, manufacturer, NB and the management of the PSUR process.

PSUR DOCUMENT: Single stand-alone document for the reporting PSUR interval that will be always attached as a PDF to the PSUR FORM and contains the data, tables and summarises the results and conclusions for the analyses of the post-market surveillance data.

Placing on the market: means the first making available of a device, other than an investigational device, on the Union market. MDR Article 2(28)

Post-market surveillance (PMS) means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions. MDR Article 2(60).

Putting into service: means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose. MDR Article 2(29).

Serious public health threat: means an event which could result in imminent risk of death, serious deterioration in a person´s state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time. MDR Article 2(66).

Similar medical devices: devices belonging to the same generic device group. The MDR defines this as a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics. MDCG 2020-6.

Legacy devices: Devices with a valid certificate issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC which are continued being placed on the market or put into service after the MDR Date of Application (DoA), 26 May 2021.