WHITEPAPER

MakroCare
New Possibilities, Everyday

Periodic Safety Update Report (PSUR) Guidance EU MDR

www.makrocare.com

medtech@makrocare.com

Periodic Safety Update Report (PSUR) Guidance EU MDR

As per Article 86 and Annex III of the (EU) 2017/745 Medical Device Regulation (MDR), Periodic Safety Update Report (PSUR) is part of the technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 throughout the lifetime of the device.

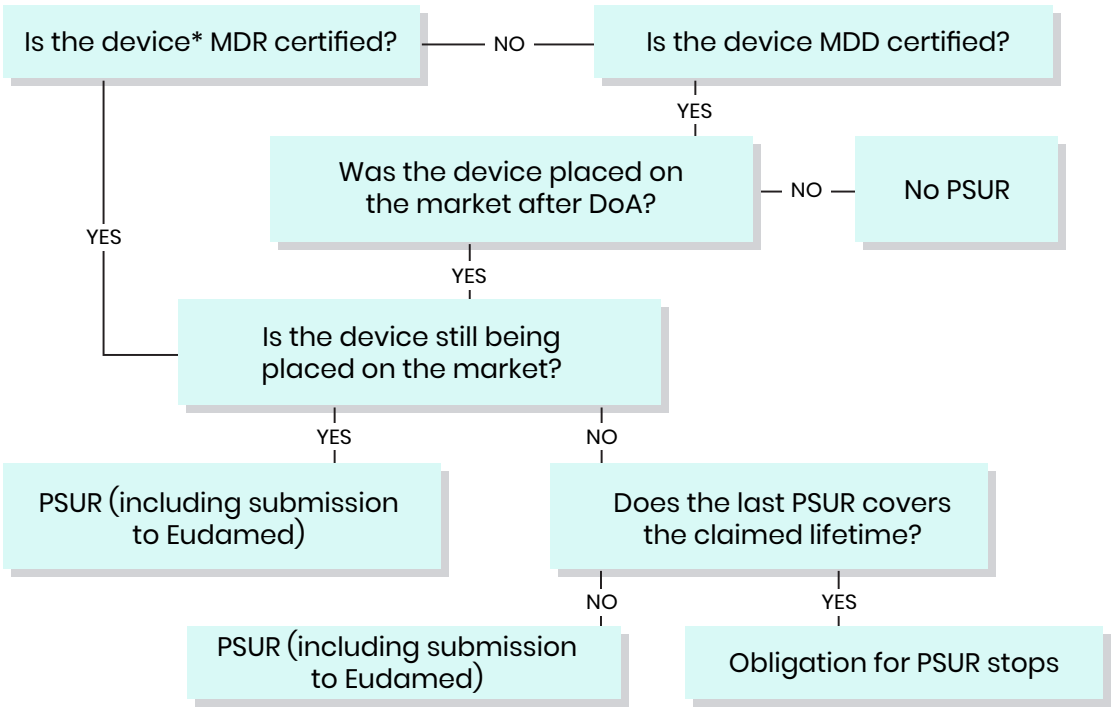
The Objective of this guidance document is to assist manufacturers of Class IIa, IIb, and III devices for more consistent, standardized and systematic review of Post-Market Surveillance (PMS) data gathered as per Post-Market Surveillance Plan to meet requirements laid down in Article 86 of European Union (EU) 2017/745 Medical Device Regulation (MDR).

In accordance with MDR requirements the PSUR should summarize the results and conclusions of the analysis through both reactive and proactive PMS data collection of a device or a device group which include:

- The volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, when practicable, the usage frequency of the device Information concerning serious incidents and field safety corrective actions
- Records referring to non-serious incidents and data on any undesirable side-effects
- Information from trend reporting;
- Relevant specialist or technical literature, databases and/or registers
- Information, including feedbacks and complaints, provided by users, distributors and importers;
- Publicly available information about similar medical devices.

Basing on the above information regarding safety and performance concerns and the findings from Post-Market Clinical Follow-up (PMCF) would be evaluated for any possible changes to the benefit-risk profile of the medical device(s).

Workflow for assessment of PSUR requirement

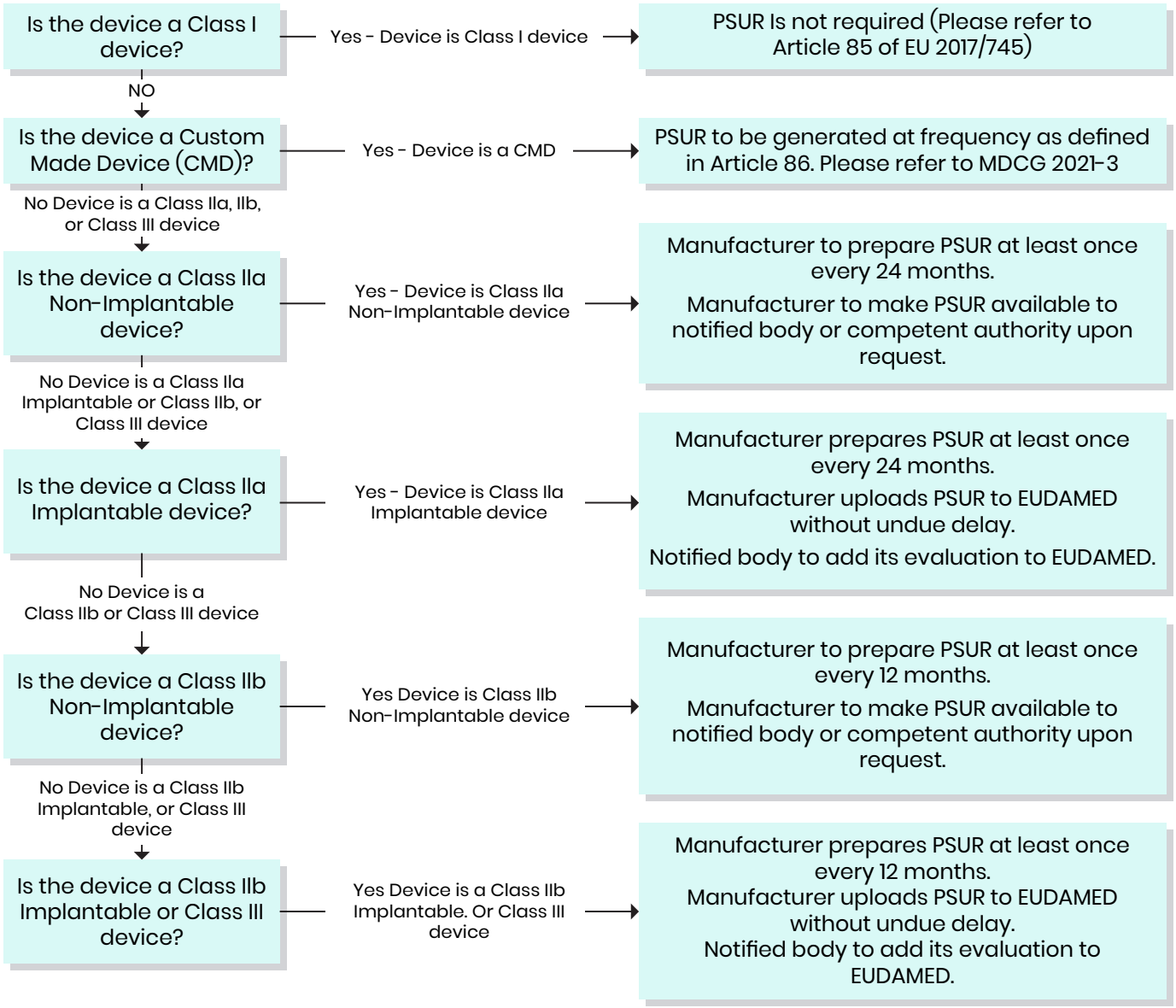


A PSUR can be documented for one device or group of devices associated with one or multiple Basic UDI-DI. In case of a group of devices covered by the same PSUR, the data should be presented in a clear, organized manner so that it is easy to determine how each device performs independently. A justification should always be provided by the manufacturer for the grouping of several devices and device families within the same PSUR.

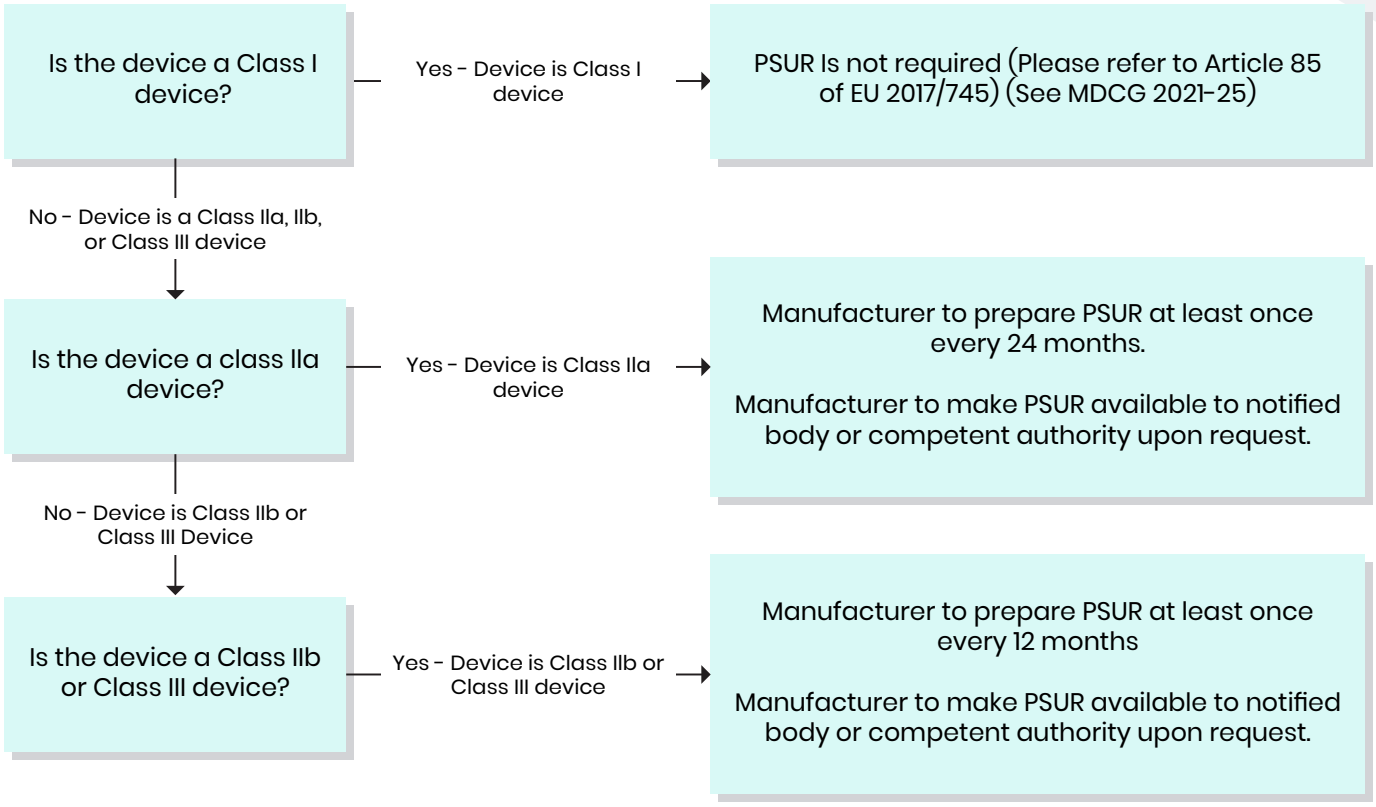
For the first PSUR as per MDR certification, the data analysis may be supported by the device's historical PMS data. The historical data may be presented in a different format than the MDR ones and could be limited to a summary. For legacy devices certified under MDD without significant change in the sense of Art 120(3), the initial PSUR schedule established under the Article 120(3) regime may continue (unless otherwise agreed between the manufacturer and its Notified Body). Therefore, the schedule for the MDR device may not align on the initial MDR certification date. If a significant change in the sense of Article 120(3) occurs, the device should be considered as a new device PSUR as per MDR new schedule needs to be started.

The data collection periods should be contiguous between the two PSURs.

Decision tree for PSURs when Medical device certified as per MDR based on their Classification



Decision tree of PSURs for Legacy Devices based on Classification



PSUR is not required, if the end of the intended lifetime of that device (last manufactured device) achieved after placing in the market. If the device's certificate expired but the lifetime of the device has not yet been covered by the last PSUR and or if the device discontinued by the manufacturer while the device's certificate has not yet expired, a PSUR at least with reactive data regarding product complaints, reporting of serious incidents, FSCA and trend reports as should continue to be made available to the notified body involved in the conformity assessment and upon request, to competent authorities.

For new MDR devices, the first PSUR should be prepared within one (class IIb and III) or two (class IIa devices) year(s) following the first Statement of Conformity for this type of devices is issued.

For class III devices or implantable devices, the manufacturers should submit PSURs through European database on medical devices (EUDAMED) to the Notified Body involved in the conformity assessment. When registering a PSUR in EUDAMED, the manufacturer should capture the Basic UDI-Dis and create PSUR reference number which should remain the same for the PSUR updates.

For non-implantable devices of either class IIa or class IIb and legacy and custom-made devices. The PSUR is not submitted to EUDAMED: manufacturers should make PSURs available to the Notified Body involved in the conformity assessment and, upon request, to the Competent Authorities.

The PSUR Web form for manufacturer contains all the relevant administrative data necessary for the registration of the PSUR in EUDAMED. Until EUDAMED becomes fully functional, manufacturers or their authorized representatives should apply the respective national provisions.

****