





ChatMDR


 My medical device is a piece of software that drives an insulin pump. It receives values from a sensor that measures the patient's blood sugar and regulates the insulin injection. The sensor and pump are 3rd party medical devices, I only interface with them. What is the classification of my software medical device?

 Your software medical device, which drives an insulin pump and regulates insulin injection based on values received from a blood sugar measuring sensor, can be classified based on its function and impact on patient management. Given the description, your software plays a critical role in the therapeutic management of the patient by adjusting insulin levels, which is vital for patients with diabetes. This adjustment is based on real-time physiological parameters (blood sugar levels) and directly influences the administration of a medicinal substance (insulin).

Considering the MDR and the provided guidance, your software falls under the category of "software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes" as per Rule 11. However, since your software's decisions have an impact that could result in immediate danger to the patient if not correctly executed (e.g., incorrect insulin dosage), it is classified at a higher risk class. Specifically, it is intended for monitoring of vital physiological parameters where the nature of variations of those parameters (blood sugar levels) is such that it could result in immediate danger to the patient (hypoglycemia or hyperglycemia).

Furthermore, your software could be considered as part of a "closed loop system" which significantly determines the patient management by the device, as it automatically adjusts insulin delivery based on the sensor readings without manual intervention. According to Rule 22, active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems, are classified as class III.

Therefore, based on the information provided and the relevant MDR rules, your software medical device would likely be classified as Class III due to its critical role in managing insulin therapy, a vital physiological process, and functioning within a closed-loop system.

 Which steps, like user or physician intervention, can I take to declassify the software to a lower class?

🌀 Declassifying your software from a higher class (e.g., Class III) to a lower class under the Medical Device Regulation (MDR) involves modifying its functionality, intended use, or the level of control it exerts over the medical device it interfaces with, such as an insulin pump. Here are several strategies that could potentially lower the classification of your software:

1. **Reduce Automation in Decision-Making:** If your software currently makes automatic adjustments to insulin delivery without user intervention, consider redesigning it to recommend insulin doses based on sensor readings but require manual confirmation by the user or a healthcare professional. This could potentially shift its classification by reducing the immediate risk associated with automated decision-making.
2. **Limit the Scope of Control:** Narrow the scope of what your software controls. For instance, instead of directly adjusting insulin doses, it could be limited to monitoring blood sugar levels and alerting the user or healthcare provider when intervention is needed.
3. **Introduce User or Physician Decision Points:** Incorporate mandatory decision points where a user or physician must review and approve any changes suggested by the software before they are implemented. This could be seen as reducing the risk of incorrect automatic adjustments.
4. **Enhance Safety Features:** Implement additional safety features and fail-safes that minimize the risk of harm due to software malfunction or incorrect data interpretation. While this may not directly lead to declassification, it strengthens the argument for a lower classification by demonstrating reduced risk.
5. **Reevaluate Intended Use:** Carefully review and possibly narrow the intended use of your software as defined in your regulatory documentation. A more specific intended use, with clear limitations on the clinical scenarios or patient populations it addresses, might support a lower classification.
6. **Consult with Notified Bodies or Regulatory Experts:** Before making significant changes, consult with notified bodies or regulatory experts. They can provide guidance on how proposed changes might affect your software's classification and advise on the best path forward.
7. **Documentation and Justification:** Prepare thorough documentation justifying why the changes in functionality, intended use, or safety features warrant a lower classification. This should include risk assessments, clinical evaluations, and any other evidence supporting the reduced risk profile of your software.

It's important to note that any changes to the software's functionality or intended use must still meet the needs of your target users and not compromise patient safety. Additionally, all changes will need to be documented and submitted to the relevant regulatory bodies for approval before they can be implemented.

👤 So if I'm only alerting, say in a smartphone app that shows a push notification to the user, what is the classification then?

- ☞ If your medical device software is designed solely to alert users, such as through a smartphone app that sends push notifications based on the monitoring of physiological parameters (e.g., blood sugar levels for a diabetic patient), its classification under the Medical Device Regulation (MDR) could potentially be lower than if it were directly controlling a therapeutic device like an insulin pump.

Based on the MDR, software that is intended to monitor physiological processes generally falls under Class IIa, as per Rule 11. However, if the software is intended for monitoring of vital physiological parameters where the nature of variations of those parameters is such that it could result in immediate danger to the patient, it is classified as Class IIb. This is particularly relevant if the software alerts are based on monitoring parameters that, if not acted upon, could lead to immediate danger to the patient's health (e.g., very high or very low blood sugar levels).

Therefore, if your app is primarily alerting the user to potential issues based on the monitoring of vital physiological parameters, without automatically adjusting or controlling a medical device like an insulin pump, it would likely be classified as Class IIb. This classification takes into account the potential risk associated with the nature of the alerts and the reliance on the user to take appropriate action based on the information provided.

It's important to note that the classification could be influenced by specific features of the software, such as the ability to provide specific recommendations, the level of interaction with other medical devices, and the intended use as defined by the manufacturer. Consulting with a notified body or regulatory expert can provide more personalized guidance based on the detailed functionality and intended use of your software.
