Deliverable 6.2

Medical Certification Concept

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Abstract

The document discusses the classification of CleverGuard in relation to the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) within the European countries. The questions addressed include whether CleverGuard qualifies as software under the definition of MDCG 2019-117. The conclusion drawn is that CleverGuard does not fall under the category of an MDR Annex XVI device, an accessory for a medical device, or software driving or influencing the use of a medical device. Consequently, it is determined that CleverGuard does not meet the criteria to be considered a medical device.

What is new in this Version

The CleverGuard project is Co-funded by the European AAL Joint Programme

Version	Date	Changes	Organization
1	Dec 23	Initial Creation	CLAP

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Content

1 Overview

The need for a medical device certificate, also known as a medical device regulatory approval or clearance, depends on the intended use and classification of CleverGuard and the regulatory requirements in the jurisdiction where it is planned to market and distribute the product. Since CleverGuard is designed to monitor electricity usage patterns in households of elderly people, and the pattern changes may be connected to changes in health and activity status, it could be considered a medical device in some situations. Here are some factors to consider:

1. **Device Classification**: The classification of medical devices varies by region or country. Typically, devices are classified into classes (e.g., Class I, Class II, Class III) based on their intended use, risk level, and potential harm to the patient or user. The classification criteria and regulatory pathways differ from one jurisdiction to another.

2. **Intended Use**: If CleverGuard would be intended for medical purposes, such as monitoring the health status of elderly individuals, it may be subject to medical device regulations. In case CleverGuard would a connection between changes in electricity usage patterns and changes in the physical and mental health and activity status of the elderly, this could be considered a medical purpose.

3. **Regulatory Jurisdiction**: The specific regulatory requirements for medical devices vary by country or region. For example, the Food and Drug Administration (FDA) regulates medical devices in the United States. The European Medicines Agency (EMA) and the European Commission oversee medical devices through the Medical Device Regulation (MDR) in the European Union.

4. **Risk Assessment**: Regulatory agencies evaluate the potential risks associated with medical devices. If the device poses a low risk to patients or users, it may be subject to less stringent regulatory requirements. However, it may require more rigorous assessment and certification if it poses higher risks.

5. **Consultation with Regulatory Authorities**: It's advisable to consult with the regulatory authorities in the relevant jurisdiction to determine whether CleverGuard requires a medical device certificate and to understand the specific regulatory pathway and requirements. They can guide the classification, testing, and certification process.

6. **Clinical Evidence**: Depending on the classification of the applicationand intended use, CleverGaurd may need to provide clinical evidence to support its safety and effectiveness, especially if it is considered a Class II or Class III medical device.

7. Quality Management Systems: Manufacturers of medical devices often need to establish and maintain quality management systems, such as ISO 13485, to ensure the consistent production of safe and effective devices.

8. Post-Market Surveillance: After obtaining certification, we may need to implement post-market surveillance to monitor the device's performance and safety in real-world use.

Given the potential health-related implications of CleverGuard, it's crucial to engage with regulatory experts or consultants who are knowledgeable about medical device regulations in the target markets. They can help CleverGuard to navigate the complex regulatory landscape and guide it through the certification process, including conducting risk assessments, clinical studies (if required), and quality assurance procedures. Ultimately, compliance with regulatory requirements is essential to ensure the safety and effectiveness of CleverGuard and to gain market access.

European medical device regulation is primarily governed by the European Union (EU) regulations. Medical devices in the EU were regulated under the Medical Devices Directive (MDD) and the In Vitro Diagnostic Devices Directive (IVDD). However, these directives have been replaced by new regulations:

1. Medical Devices Regulation (MDR): The EU MDR (EU 2017/745) applies to medical devices and regulates their marketing and distribution in the European Union. The MDR became fully applicable on May 26, 2021.

2. In Vitro Diagnostic Devices Regulation (IVDR): The EU IVDR (EU 2017/746) is specific to in vitro diagnostic devices and became fully applicable on May 26, 2022.

Under these regulations, a Notified Body is designated by each EU member state to assess and certify medical devices for conformity with the regulations. These Notified Bodies are accredited and authorized to perform conformity assessments and grant CE marking, which is required to market and sell medical devices in the EU.

Here's how this process generally works in the countries of the CleverGuard Consortium:

Switzerland: Switzerland is not an EU member state but is closely aligned with EU regulations. Medical devices in Switzerland are regulated by Swissmedic, which collaborates with EU Notified Bodies for conformity assessments. Manufacturers can apply for Swiss medical device approvals, which are often based on the CE marking obtained through an EU Notified Body.

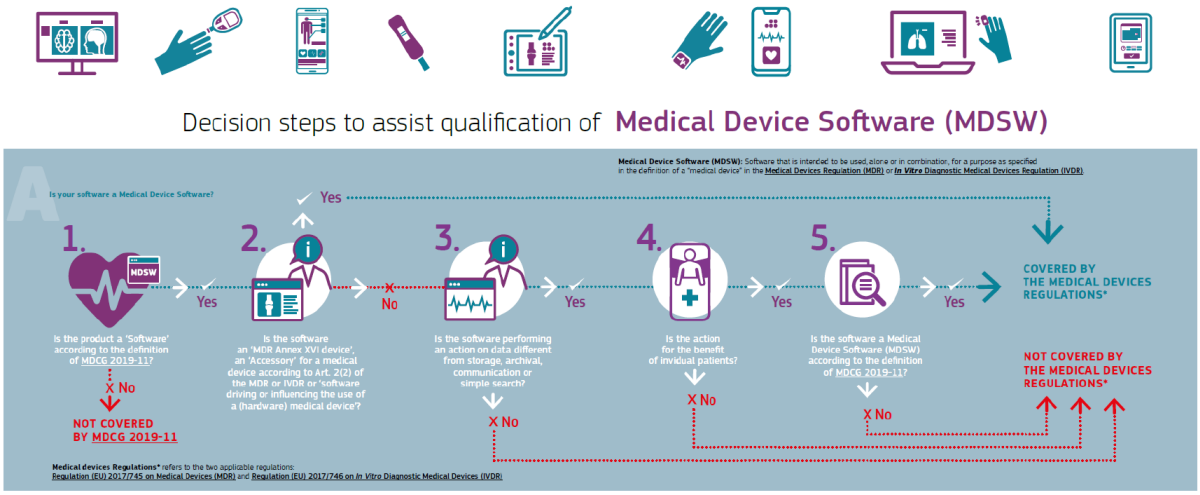
Italy: Italy follows EU regulations for medical devices, and the Italian Competent Authority oversees compliance. Notified Bodies in Italy also play a role in assessing and certifying medical devices.

Hungary: as an EU member state, Hungary follows EU regulations for medical devices. The Hungarian National Authority for Medical Devices and Medicinal Products (OGYÉI) is responsible for regulatory oversight.

Belgium: Belgium also follows EU regulations for medical devices, and the Belgian Federal Agency for Medicines and Health Products (FAMHP) is involved in regulatory matters.

Rest of Europe: The rest of Europe follows the EU regulations for medical devices, with each country designating Notified Bodies responsible for conformity assessments. However, it's important to note that some non-EU European countries, such as Norway and Iceland, participate in the European Economic Area (EEA) and align their regulations closely with EU requirements.

2 Medical Device Software Assesment



Questions to be answered in detail:

- Point 2 in the diagram above: Is the product a «Software according to the definition of MDCG 2019-117"
    - CleverGuard is not an MDR Annex XVI device, nor an accessory from a medical device, nor a software driving or influencing the use of a medical device.
- Point 3 in the diagram above: Is the software an "MDR Annex XVI device", an "Accessory" for a medical device according to Art. 2(2) of the MDR or IVDR or "software driving or influencing the user of a (hardware) medical device?
    - CleverGuard is not an MDR Annex XVI device, nor an accessory from a medical device, nor a software driving or influencing the use of a medical device.

Due to the above we conclude that CleverGuard is not a medical device and needs not to undergo the medical certification.