PRACTICAL APPLICATION OF A METHODOLOGY FOR MEDICAL DEVICE CLASSIFICATION UNDER THE EU MDR

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Abstract. Medical device classification under Regulation (EU) 2017/745 (MDR) remains difficult in practice, especially for software, reusable surgical instruments, and borderline products. This study presents a structured methodology that translates Annex VIII into a top-down decision sequence based on 72 binary sub-identifiers. The method combines base-category identification, selection of the applicable MDR rule, and progressive refinement through yes/no decision points. Representative marketed devices, including dental tampons, physiological-monitoring mobile applications, and surgical instruments, were evaluated to demonstrate how the approach resolves ambiguous interpretations and produces reproducible class assignments. The results show that the methodology improves traceability, clarifies Notified Body involvement, and reduces the risk of misclassification during design and conformity assessment. The framework is suitable for engineering teams and can support future automation of regulatory decision-making.

Keywords: medical devices, EU MDR, classification, conformity assessment, regulatory compliance, medical software, risk management

1. Introduction

Medical devices are engineering products whose design must satisfy both technical performance requirements and a stringent regulatory framework. Under Regulation (EU) 2017/745 on medical devices (MDR)[1], classification is the first decisive regulatory step because it determines the conformity-assessment route, the extent of technical documentation, and the possible involvement of a Notified Body[2] (Fink & Akra 2023; Peter et al. 2020).

Although Annex VIII of the MDR defines 22 classification rules, their direct practical application is often challenging for manufacturers and engineers. Ambiguity is especially visible for medical software under Rule 11, reusable surgical instruments, and borderline products in contact with body orifices. In practice, the wording of the rules may permit different interpretations, which increases the risk of inconsistent classification and delayed market access[1, 2] (Fink & Akra 2023).

The problem is not purely formal. Medical devices interact directly with the human body and therefore even minor design, material, software, or performance deviations can have significant consequences for patient safety. Engineers must simultaneously account for functional effectiveness, biocompatibility, reliability, risk management, and regulatory compliance throughout development (Peter et al. 2020; Bianchini & Mayer 2022).

Within the European Union, the MDR replaced the earlier Directives 90/385/EEC[3] and 93/42/EEC[4] and introduced a clearer risk-based structure with Classes I, IIa, IIb, and III. Newer rules, including Rule 11 for software, Rule 19 for nanomaterials, and Rule 21 for substances introduced into or absorbed by the human body, may lead to higher classification because of their safety implications[1, 2].

This study examines a structured methodology for medical device classification that formalizes Annex VIII into a traceable decision path based on 72 binary sub-identifiers. The aim is to demonstrate, through practical case studies, how the method reduces subjectivity and supports reproducible class determination for marketed devices with potentially ambiguous regulatory status.

2. Materials and methods

2.1. Regulatory and methodological basis

The proposed approach builds on the MDR classification framework[1, 2] and on prior work that introduced additional logical refinement through binary sub-identifiers (Arsov 2025). The method addresses a frequent practical problem: a single device may appear to satisfy more than one rule, while the rule wording itself often contains conditional language that leaves room for subjective interpretation. By converting the rules into explicit yes/no decisions, the methodology supports objective and repeatable classification[2] (Peter et al. 2020; Arsov 2025).

2.2. Structured classification methodology

The methodology is implemented as a top-down sequence of three steps:

1) Determination of the device base category according to its mode of action, such as non-invasive, invasive, active, or a specific case involving substances or software.
2) Identification of the primary MDR rule that best corresponds to the device intended purpose, duration of use, and interaction with the human body.
3) Refinement through a system of 72 binary sub-identifiers that progressively narrows the decision path until a single reproducible class is obtained.

This decision logic is designed to be engineer-ready and suitable for future automation. It can be applied during the design phase, before formal conformity assessment, to reduce misclassification risk and clarify the expected documentation burden (Peter et al. 2020; Arsov 2025).

2.3. Case-study evaluation

Representative marketed devices were selected to test the method across different regulatory contexts. The cases include dental tampons as orifice-contact consumables under Rule 5, physiological-monitoring mobile applications under Rule 11, and surgically invasive instruments under Rule 6. For each case, the decisive sub-identifiers were recorded and the resulting class was compared with plausible market interpretations and published classification examples[5] to highlight practical consequences for compliance.

3. Results

3.1. Dental tampons

Dental tampons are commercially available devices intended to absorb saliva and blood during dental procedures. Despite identical intended use, similar products can be found on the market with different regulatory presentations. One product bears the number of a Notified Body, suggesting classification at least as Class Is or IIa, while another comparable product is marketed as Class I without Notified Body involvement (Figures 1 and 2). This discrepancy indicates inconsistent self-classification, most likely related to sterility claims, assumptions about bodily-fluid contact, or conservative marketing choices.

The case illustrates how vague interpretation of Rule 5 can create unnecessary differences in regulatory burden. Applying the structured methodology (Figure 3) makes the

decision path explicit and shows how the presence or absence of specific characteristics, such as sterility, drives the final class assignment. The method therefore helps distinguish genuine risk-related differences from documentation or interpretation artifacts.



Figure 1 – Example of a commercially available dental tampon package with a Notified Body number, indicating classification as Class Is or IIa. This higher classification may result from sterility, perceived increased risk, or marketing considerations, despite identical intended use to Class I devices



Figure 2 – Example of a similar dental tampon with identical intended use but classified as Class I (non-sterile) and CE marked without Notified Body involvement, illustrating classification inconsistencies in the market

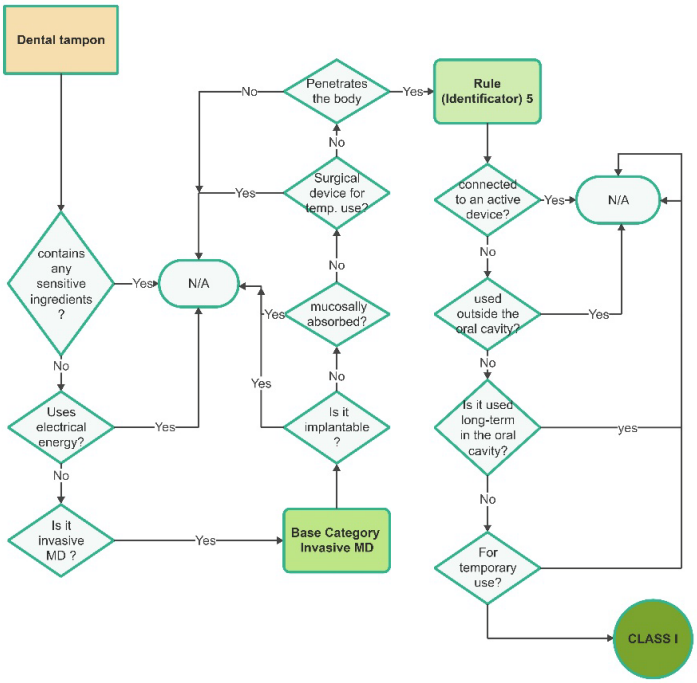


Figure 3 – Application of the proposed classification methodology to dental tampons, demonstrating how binary sub-identifiers guide toward an objective and reproducible class assignment

3.2. Mobile applications for physiological monitoring

Some mobile applications for physiological monitoring are still marketed with underestimated regulatory status. However, when the software output is used to support diagnosis, adjust therapy, predict complications, or remotely monitor patients, Rule 11 generally leads to Class IIa or IIb depending on the significance of the information for clinical decision-making and the risk posed to the patient[2, 6] (Cepeda Zapata et al. 2023).

A pivotal decision point concerns whether the software monitors vital physiological parameters and whether the generated information can influence therapeutic action (Figure 4). When vital data such as heart rate, oxygen saturation, or respiratory rate are used in a way that can drive therapy, the regulatory consequences are more stringent. Skipping one of these logical steps may incorrectly lower the class and, with it, the expected level of safety and documentation.

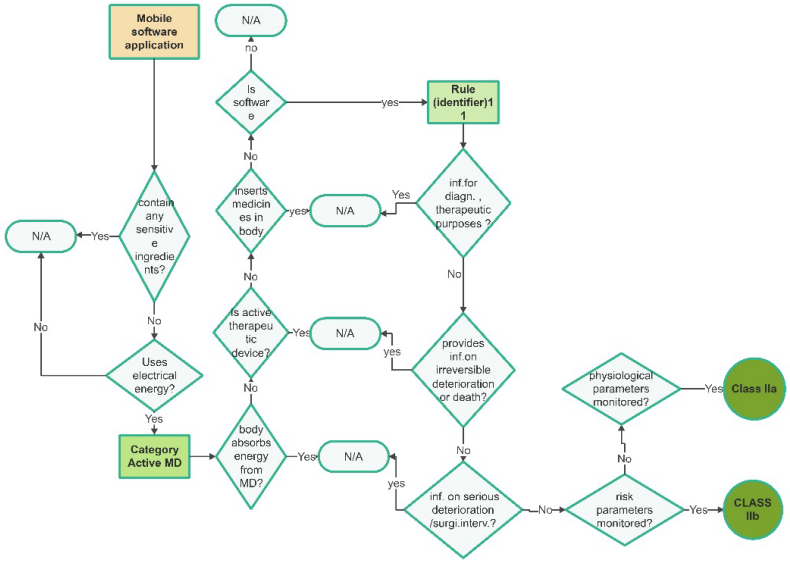


Figure 4 – Logical structure for classification of mobile applications for physiological monitoring under the MDR, focusing on Rule 11. The binary decision path determines whether the software is Class IIa or IIb based on medical purpose, type of monitored data, and impact on therapeutic decision-making

Table 1 – Classification outcomes for representative devices

Case	Primary MDR Rule	Key sub-identifiers (examples)	Resulting Class	Regulatory impact (examples)
Dental tampons (non-sterile)	Rule 5	Oral mucosa contact; transient; not connected to active device; non-sterile	Class I	Self-declaration; no NB
Mobile app for therapy via vital monitoring	Rule 11	Medical purpose; vital monitoring; influences therapy	Class IIb	NB; software life-cycle evidence; clinical evaluation
Mobile app trending non-vital data	Rule 11	Medical purpose; non-vital monitoring; no therapy impact	Class IIa	NB; lower burden than IIb
Surgical scalpel, single-use	Rule 6	Surgically invasive; transient; not in contact with CNS/heart	Class IIa	Performance verification
Surgical scalpel, reusable	Rule 6 + reusable provision	Reprocessing; re-sterilization	Class Ir	NB limited to reusability

3.3. Classification outcomes

The proposed decision logic was also applied to representative marketed devices spanning orifice-contact consumables, software, and surgically invasive instruments. Table 1

summarizes the decisive sub-identifiers, the corresponding MDR rule, and the resulting class. These device groups were selected because they are frequently misclassified in practice and therefore provide a useful test of methodological consistency.

4. Discussion

The case studies confirm that classification operates as a regulatory anchor for engineering decisions. Once the class changes, the downstream implications also change: required testing, technical documentation depth, clinical evaluation expectations, and Notified Body involvement all become more or less demanding. This is particularly visible for software and reusable instruments, where apparently small differences in intended purpose or reuse characteristics can shift the regulatory pathway substantially[2, 7] (Peter et al. 2020). For reusable instruments in particular, validated reprocessing and re-sterilization become decisive design inputs (Josephs-Spaulding & Singh 2021). More generally, harmonised and international standards act as the practical link between legal requirements and engineering practice – a role that has also been demonstrated in other regulated product sectors, such as construction (Ilieva-Mihaylova 2025).

The analysis also shows that misclassification is not a minor administrative issue. Under-classification may lead to insufficient safety justification and incomplete documentation, while over-classification may impose unnecessary certification costs and time burdens[8, 9]. The dental tampon example highlights inconsistent market practice, and the software example shows how a missed decision point under Rule 11 can lower the apparent class inappropriately.

A central strength of the proposed methodology is that it converts legal wording into a logical sequence that different specialists can follow in the same way. By formalizing the decision path through binary sub-identifiers, the method improves objectivity, reproducibility, and traceability. This is especially valuable for borderline devices and hybrid technologies, where intuitive interpretation is least reliable (Peter et al. 2020; Arsov 2025).

The present study remains focused on representative practical cases rather than a large statistical sample. Nevertheless, the results indicate that a structured and engineer-oriented framework can improve consistency when compared with direct, unaided use of Annex VIII alone. Future work should integrate the logic into digital decision-support tools for faster preliminary classification during product development.

Conclusions

Medical device classification under the MDR is a technically important process with direct consequences for safety, conformity assessment, and time to market. The methodology presented here transforms the classification task from an intuitive interpretation exercise into a systematic decision framework based on base-category selection, primary-rule identification, and refinement through 72 binary sub-identifiers.

Applied to representative marketed devices, the framework clarified ambiguous cases and produced reproducible class assignments aligned with MDR logic. The results support its use as a practical tool for engineering teams and manufacturers seeking earlier, more objective regulatory decision-making. Its future digital implementation could further strengthen consistency and efficiency in conformity assessment.

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NOTES

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