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Regulatory challenges of certification of implantable BCI medical devices in the EU and how to overcome them

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ABSTRACT: Brain Computer Interface (BCI) technology has seen substantial growth over the past decade with increasing private investment into its research and development. With ongoing promising clinical studies, market entry of implantable devices is not far in the future and so regulatory discussions now start to become relevant. All medical devices in the EU fall under the scope of the Medical Device regulation 2017/745 (MDR) and potentially the AI Act 2024/1689. So how will certification work for this technology? What will be the expected challenges considering the current regulatory framework? With focus on the clinical assessment part of certification, this article will try to navigate these questions and provide clarity to the process.

INTRODUCTION

On May 2017 the Medical Device Regulation (MDR)[1] was published by the European Commission, replacing the Medical Device Directives that were previously in place. Originally planned to come into force by 2020, due to the COVID pandemic, this was delayed to May 2021. On December 2025, much earlier than initially expected, a proposal for revision of MDR [4] was published with the purpose to remove hurdles for marketing novel technologies and breakthrough devices, thus allowing more innovation in the European Union, however there are no set dates for its implementation until now.

In the EU, the medical devices' certification process has long been privatized, with the main stakeholders being Manufacturers and Notified Bodies (NB). The latter are companies that perform the conformity assessment procedures and are responsible for issuing the certificate, allowing the manufacturers to place medical devices on EU market. The NB operates in an independent and impartial manner**,** being forbidden to provide consultancy and being regularly audited by the competent authorities in the country they are based on.

During the conformity assessment procedure different experts will review the technical documentation submitted by the manufacturer. Clinical assessment is one of the areas of review with its core being laid down in MDR [1] article 61 and Annex XIV.

The MDR also established the creation of the Medical Device Coordination Group (MDCG), which has released several guidance papers to help all stakeholders navigate the requirements of the regulation. In December 2025 the MDCG guidance on Breakthrough Devices [3] was published, finally filling in a gap in the EU certification process, by establishing an official pathway and guidance for this kind of designation and conformity assessment.

The MDR [1] provides framework for creation of the Expert panels [currently under EMA] to provide scientific opinions in pre-set circumstances foreseen by the regulation. For the purposes of this paper, only their role with Breakthrough devices will be addressed below.

On July 2024, the EU published the AI Act [2]. It came into force in August that same year with a planned phased implementation until August 2027. Medical devices incorporating software are now required to comply with both MDR and AI Act provisions.

Implantable Brain Computer Interface (BCI) medical devices will be subject to conformity assessment under the MDR and AI Act. Given their high novelty degree and expected positive clinical impact on irreversibly debilitating diseases, they can also fit the breakthrough device criteria set in the EU. Until now, no specific guidance or special certification pathway for BCI medical devices exists in the European Union, so this article will look into the current regulatory framework.

MATERIALS AND METHODS

This paper will describe how the conformity assessment procedure needs to be done for class III implantable devices such as implantable BCI, considering the current requirements of MDR [1], AI Act [2] and MDCG for Breakthrough Devices [3].

Focus will be on the clinical assessment part of the procedure.

Potential regulatory challenges (and solutions) will be discussed, also taking into consideration the most recent proposed MDR changes [4].

RESULTS

BCI as active implantable neurological devices are class III [high risk] under Annex VIII of MDR [1]. This means that they are required to have a pre-market

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clinical investigation under article 61, and although this article establishes some exceptions to this rule, for a high-risk device initially entering the European market [i.e. not CE marked before] the only one that could potentially apply would be Equivalence [Art 61(4) and 61(5)]. However, for the first few implantable BCIs applying for certification, this is not a viable option because of the lack of equivalent devices already on the market. Of note, devices only marketed outside of Europe would not qualify for equivalence in the case of a high-risk implantable medical device.

According to MDCG 2025-9 [3], in order to have their device be designated as a breakthrough device in the EU, manufacturers should request scientific advice from the EMA Expert panel established in accordance with MDR article 106 [1]. An opinion on the breakthrough status of a medical device can be requested from the Expert panel at any time of device development and once designated, this will remain valid even if, between the designation and the certification, similar devices enter the market. The proposed MDR revision [4] might introduce a small change to this pathway, that will be discussed below.

Being designated as a breakthrough device allows for special benefits such as targeted scientific input, prioritization by NB and a conformity assessment done under the considerations laid down in MDCG 2025-9, meaning, among other points, accepting a potential lower amount of pre-market clinical evidence [provided there is clear evidence of a positive benefit-risk ratio] and putting more emphasis on post-market follow-up. All this acknowledges the potential high clinical benefit of such devices, and potential treatment improvements in patients otherwise lacking sufficient medical treatment.

In November 2025 CORE-MD consortium (Coordinating Research and Evidence for Medical Devices) published their recommendations for clinical investigations of high-risk medical devices [5]. Despite not being legally binding, these overall align with MDCG 2025-9, as for breakthrough devices, a single arm observational study might suffice for certification.

So, although there may be limitations on available pre-market clinical evidence, such as but not limited to, a small cohort of patients or a short follow-up time considering the lifetime of the device, as long as a) the benefit-risk is positive and b) there is a solid post-market clinical follow-up (PMCF) plan to collect further evidence that will fill in the pre-market gaps, this would be sufficient to enter the European market.

Under Annex XIV of the MDR [1], manufacturers are required to create a Clinical Evaluation Plan (CEP) which, among other points, should establish performance and safety outcome parameters for their device. These outcome parameters are derived from State-of-the-art (SOTA) literature addressing similar devices or alternative treatment methods and need to have acceptance thresholds to allow an objective assessment of the subject device's clinical data against what is expected from SOTA. The premarket clinical study endpoints should also for the most part align with these outcome parameters. Defining appropriate clinical outcome parameters and their thresholds is one of the challenges with BCI technology, that we'll also look into more detail below.

As previously mentioned, medical devices using artificial intelligence algorithms must comply with AI Act [2]. MDCG 2025-9 [3] also addresses breakthrough medical devices with AI, as it states manufacturers are expected to "ensure that the clinical evidence adequately demonstrates the performance, reliability, and generalizability of the medical device AI within its intended purpose and intended use environment". Furthermore, "this evaluation should take into account the dynamic characteristics of AI". Again, the proposed MDR revision [4] also introduces some changes to the interplay of MDR and AI Act, like shifting the MDR from Section A in the AI Act to Section B – which reduces the actual relevance of the AI Act but strengthens the requirement to follow the MDR.

DISCUSSION

Implantable BCI medical devices have a high degree of novelty with at the same time a high expected clinical benefit, which makes them suitable for Breakthrough Device designation in the EU. This will mean the acceptability of the higher uncertainty that comes with a high novelty degree, provided there is a clear clinical benefit and the risk profile is acceptable. Perhaps more than for other devices, for breakthrough technologies, post-market becomes extremely relevant. A solid PMCF Plan - MDCG 2020-7 [6] - accounting for device-specific clinical data collection from large(r) cohorts and with extended follow-up will be expected [e.g., device registries or activities following up on the majority of implanted patients]. Assessment of this post-market data will also be conducted at regular intervals by the Notified Bodies, the timeframe for which will ultimately depend on the type of clinical data gaps at initial certification.

The proposed MDR revision [4] introduces article 52(a) to specifically address breakthrough and orphan devices. On point 4 this article states "Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 shall provide an opinion as to whether the criteria set out in paragraph 2 or 3 of this Article, as applicable, are fulfilled" thus not clearly stating the mandatory requirement of designation through the Expert panel [it would alternatively be a NB's decision]. As it is expected that this proposed MDR changes will undergo text revision before official publication, hopefully this will become clear by then. However, until the revised MDR is published, and this is not foreseen before the next one or two years, the current one and associated MDCG papers remain in place, meaning that current guidance of MDCG 2025-9 [3] shall be followed.

It is also important to notice that the proposed revision

10.3217/978-3-99161-093-9-001

also recognizes the panel's opinion as non-biding by stating in article 52(a) 6 "The notified body shall give due consideration to an opinion or advice provided by the expert panels in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided". The proposed revision also for the most part aligns with MDCG 2025-9 [3] specifically on the prioritization of these assessments by NB [art 52(a)6] and the acceptance of limited clinical data provided acceptable benefit-risk and solid PMCF Plan [art 52(a)7].

Early engagement in structured dialogues with NB [also encouraged by MDCG 2025-9] will be key to not only navigating the pathway for breakthrough designation but also, from an early stage, initiating discussions on available data, as, even without providing direct consultancy, NB can discuss available evidence.

What will be suitable outcome parameters for implantable BCIs is a matter of great discussion within the "BCI community". Because AI is a big component of these devices technical outcomes [e.g., speech rate as in words per minute] are inevitable, however, they need to be combined with more clinical ones as to actually translate the expected clinical benefit, these latter will most likely need to include at least some patient reported outcomes, especially whenever the BCI is addressing symptom improvement in debilitating conditions. Establishing acceptability thresholds for these parameters will be an additional challenge though. As previously mentioned, these should derive from SOTA, but what if there is nothing to compare them with? No similar devices and no possible direct comparison with alternative treatments? In such cases, even though alternative treatments might not be the ideal comparison, they are still the only option to provide approximate threshold values for the clinical parameters, especially for the safety ones, which most likely will address procedure complications. As more BCIs enter the market though, they will become points of comparison to each other.

Finally, regarding AI Act and proposed MDR revision the following is stated in the latter "To prevent those overlaps and to simplify the regulatory framework for artificial intelligence-enabled devices, the application of Regulation (EU) 2024/1689 to those devices should be limited to those provisions referred to in Article 2(2) of that Regulation" Should be noted that this, although somehow simplifying the process, does not contradict the statements in MDCG 2025-9.

CONCLUSION

Navigating what sometimes seems like rapidly changing and even contradictory requirements is not an easy task for any of the stakeholders involved in certification of medical devices.

Additionally, the first implantable BCIs will have the unique challenge of setting appropriate outcome parameters, a challenge not only from a clinical perspective but also from a regulatory one.

To mitigate these challenges and smooth the conformity assessment procedure, early engagement and discussions with NB are essential and should not be underestimated.

These are exciting times for neurological devices. Despite the challenges discussed, one thing that we can all agree is that fostering innovation and allowing patients access to groundbreaking technology is definitely possible with the EU regulatory framework, especially given the most recent published guidance and proposals.

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