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The designation of notified bodies under the upcoming Artificial Intelligence Act

Background

Artificial Intelligence (AI) algorithms, in its various forms, machine learning, deep learning, etc., implemented as embedded software (SW) or standalone SW, are gaining in popularity in the healthcare sector. These techniques are driving new trends in the medical industry, enabling, and supporting healthcare professionals to control or automate complex processes, such as supporting radiologists in filtering abnormal images. Proper deployment of these technologies could further enable efficient and accurate diagnosis, therapy and facilitate the development of personalised treatments utilizing large datasets, with care aligned to patients' individual needs, with future potential implications being effective and more affordable healthcare sector solutions.

The importance of enabling these technologies has been also recognized by other regulatory authorities such as the US FDA which has increased the effectiveness of the authorization process for AI-enabled medical devices to reduce the time-to-market for the medical devices (MD) and facilitate innovation[1].

Current and future regulation of AI in medical devices

As with many technological advancements, AI presents benefits as well potential risks. Although many medical devices using AI have already been approved, the regulatory pathways do not follow an established and systematic approach as the underlying requirements of the systems, data and skills are rapidly changing. To address these challenges, the European Commission published a new proposal for a regulation that covers rules on AI in April 2021 (Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS COM/2021/206 final). The draft Artificial Intelligence Act (AIA) is a horizontal regulation implementing a risk-based approach which categorises AI-enabled systems based on different levels of risk and to identify the level of control on AI Systems being placed on the European market. According to the draft Regulation high-risk AI systems, which include medical devices and in-vitro diagnostic medical devices, must undergo a conformity assessment procedure. The conformity assessment must be performed by designated notified bodies (NBs).

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[1] FDA approved AI/ML medical devices: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Challenges with designating notified body already under NLF designation

According to AI Act Article 31, the NBs shall apply for notification to the notifying authority of the Member State in which they are established, to be entrusted with the assessment of the AI. As per article 32 covering the Notification Procedure, the notification/designation may be granted only to the conformity assessment bodies which have satisfied the requirements laid down in Article 33. The existing competence and the augmentation of the existing competence, of MDR/IVDR designated notified bodies, are apparently not being recognized, even though the NBs have already been addressing this challenge by having developed a systematic approach on assessing those medical devices and in-vitro diagnostic devices with AI.

Article 33 of the AI Act lists twelve requirements for the NBs for the assessment of the AI driven devices such as medical devices and in-vitro diagnostic medical devices. The requirements of Article 33 to be met by the NB are rather general, the NBs shall provide appropriate evidence for claimed competence, appropriate organizational structure, availability of resources and a defined procedure or systematic approach for AI conformity assessment. The relevance of the requirements stipulated by the Article 33 is consensually agreed – there are however concerns of additional burden for the NBs for implementing redundant measures that are already implemented for the designation under MDR and IVDR.

As per Annex VII – "Requirements to be met by notified bodies" (MDR), all designated NBs are obliged to continuously update their procedures & workflows according to e.g., §3 Resource Requirements or §4 Process Requirements to be aligned with the state of the art, and able to effectively perform the assessments & audits. AI is increasingly adopted by the manufacturers of MDs and as a response the NBs have already triggered activities to align with the specific requirements of this new technology. Technical and quality management system considerations which are outlined in the AIA Chapter 2, 3 and Annex IV, are only representing a technology specific part of the conformity assessments already conducted by MDR/IVDR appointed NBs during audits and technical file reviews. As of today, the NBs already perform assessments of AI driven MDs and audit their manufacturers, suppliers, etc, allowing the manufacturers to legally place such devices on the market under MDR/IVDR.

Furthermore, it is speculated, that those medical devices which would be considered high-risk AI under the AIA, would be also categorized in higher safety classes under the regulations. (MDR Class IIa/IIb/III / IVDR Class B, C, D). The implication for the manufacturers is that they must follow rigours clinical evaluation and post-market activities which are already mandated by the MDR and IVDR (see e.g., MDR Art. 61, Annex III and Annex XIV). During the conformity assessment procedures, manufacturers are required to demonstrate that the intended clinical performance (such as diagnostic accuracy) and safety (such as risks, security, bias, oversight, foreseeable misuse etc.) of their devices are maintained throughout the product life cycle via sufficient clinical data. (e.g. MDCG

2020-6[2]). These are for example assessed as part of the technical file reviews (MDR/IVDR annex II) conducted by qualified personnel of the appointed MDR/IVDR NBs. Therefore, the conformity assessments performed by the medical NBs consider both the intended purpose of those devices and the underlying technologies, including those of AI approaches. This concludes that the requirements outlined in AIA can be sufficiently covered by already appointed MDR/IVDR NBs assuming the availability of appropriate resources and qualified personnel.

There are serious implications we see with the release of the official AIA. The manufacturers having AI driven MDs placed already on the market, will suddenly have no NB allowed to process their change requests, vigilant cases, etc, during the designation process. New manufacturers promoting the AI technology, on the other hand, will not be able to enter the market at all, depriving the European population from having access to the latest technologies.

Concluding, the additional bureaucratic burden, caused by the AIA will have an undesirable impact to the already limited number and capacity of NBs, as the NBs will need more resources to be invested for new designation, rather than for building the internal competence for assessment of AI in medical devices, a process that is already undertaken by the NBs.

Team NB position
Software, either as a medical device on its own right or as part of a medical device, is already covered under the regulations (MDR/IVDR) and is assessed by the appointed MDR/IVDR NBs following the desired conformity assessment routes, considering both the intended purpose of the devices, benefit-risk determination, and underlying technologies.

The AI technology, even if implemented as SW, is recognized to have certain specificities compared to the classical SW. While the classical SW driving MDs is mainly implementing deterministic algorithms, the AI decision making is a stochastic process, i.e., based on statistics & probabilities. There are additional aspects to be considered for the development of AI driven MDs. These technical aspects, however, can be further detailed and specified as part of the already existing conformity assessments procedures of MDR/IVDR.

There is agreement among the Team NB members that additional technical expertise is needed for the assessment of AI. The process of updating the processes & skills by NBs to accommodate AI is ongoing and done according to the requirements of e.g. Annex VII – MDR §3 Resource Requirements or §4 Process Requirements. The NBs for medical devices and IVDs have already implemented authorization procedures to accommodate technical changes of the state-of-the -art.

An update of the processes & personnel competence to align with the AI requirements is seen as essential for the NBs, but not done in the context of a complete designation, which may have serious implications as previously indicated. Instead, we see as more appropriate and effective to use the existing authorization framework to accommodate AI. The appointed NBs may implement ways, following the MDR/IVDR rules, to also cover certain essential requirements outlined in AIA. A

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[2]MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for manufacturers and notified bodies: https://ec.europa.eu/docsroom/documents/40904

possible approach may be to limit the existing scopes in case certain AIA specific requirements are not fulfilled as stated in MDCG 2019-4 §3, or to introduce new scopes specific for AI under MDR/IVDR.

The position paper is fully aligned with the recommendations by the European Commission stipulated in the MDCG 2022-14 "Notified Body capacity and availability of medical devices and IVDs" – August 2022, which recognises the current challenges with the transition to MDR/IVDR and propose actions to enhance NBs capacity and avoid shortage of medical devices, e.g. the action §9 in which is indicated MDCG to explore means to add codes to the designation of notified bodies in timely manner in accordance with the regulations.