MEDTRONIC SUBMISSION
ARTIFICAL INTELLIGENCE REGULATION
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Executive Summary

Medtronic, as a global leader in medical technology, strongly supports the principle of EU-wide regulation of Artificial Intelligence (AI) and welcomes the Commission's vision to turn Europe into a global hub for AI and further develop a resilient Europe fit for the Digital Decade.

Medtronic views the interface between the proposed AI Regulation, GDPR, MDR and IVDR as critical to the future of the medical device industry. Our review of the proposed AI Act has identified areas where duplication or overlaps could appear and therefore, we respectfully offer several recommendations to the European Commission to ensure seamless interplay between those Regulations:

- Recommendation 1: Amend Article 13 of the proposed AI Regulation to explicitly confirm that the information provided on the basis of Article 13 is sufficient in order to enable the assessment under Article 35 GDPR to be undertaken.
- Recommendation 2: Amend Article 63 of the proposed AI Regulation to provide that the Competent Authorities under MDR and IVDR have sole competence for regulating high-risk AI products within their sectoral remit, including any aspects of the proposed AI Regulation that may apply to those products.
- Recommendation 3: Do not apply Article 24 of the AI Regulation to medical devices to avoid conflict with similar provision under MDR/IVDR.
- Recommendation 4: Amend Article 43(3) of the AI Regulation to stipulate that the notified body performing the conformity assessment under the AI Regulation shall be the same notified body as the one designated under MDR/IVDR.
- Recommendation 5: Stipulate that medical device manufacturers shall be deemed to have complied with Articles 9, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23 and 25 of the AI Regulation by complying with the corresponding provisions of MDR/IVDR (as set out in this document).
- Alternative Recommendation 5 for Article 14: If it is considered desirable for device labelling or instructions for use to specifically identify the matters set out at Article 14(2) of the AI Regulation, these could be included by way of an amendment to section 23 of Annex I MDR and section 20 of Annex I IVDR.
- Clarification Request: Clarify how the result of conformity assessment from both regimes (MDR / IVDR and the AI Regulation) will be reflected in a final declaration of conformity.

We expand on these points in this paper and remain available to the Commission, and other interested stakeholders, to further discuss our position and recommendations.

Medtronic

Introduction

Medtronic plc, headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world.

In the EU and across the globe, smart medical devices and AI technologies are moving to the forefront of healthcare. As healthcare systems grapple with how to provide quality care in the most efficient, cost-effective way, both AI and machine learning are playing increasingly important roles in making that a possibility.

Smart devices allow providers to tap into enormous amounts of data and can help improve the health of patients with chronic and expensive health conditions like diabetes. But sifting through that data is no small feat. AI, machine learning, and predictive modeling are often the engines that drive that important work.

We are committed to leveraging data and insights to deliver on a whole new vector of innovation with digital technologies, there is huge opportunity to harness the power of AI and other technologies that are redefining the relevance and value of our therapies.

Medtronic is therefore deeply invested in the advancement of AI for medical devices in the European Union and welcomes the opportunity to provide feedback on the European Commission's proposed AI Regulation published on 21 April 2021 (the "AI Regulation") in the context of the Commission's feedback mechanism.

This document follows the initial submission made by Medtronic on 13 June 2020 as part of the European Commission's consultation on the EU White Paper on Artificial Intelligence. It focusses on the interplay between the AI Regulation, GDPR and regulations specific to the medical device industry, namely the EU Medical Devices Regulation 2017/745/EU ("MDR") and the EU In Vitro Diagnostics Medical Devices Regulation 2017/746/EU ("IVDR").

For more detailed feedback on some of the substantive requirements of the proposed AI Regulation, Medtronic refers to the submission made by MedTech Europe on behalf of its members, to which Medtronic contributed and hereby endorses.

EU-wide regulation of AI

Medtronic strongly supports the principle of EU-wide regulation of AI and recognises that whilst the technology brings substantial benefits to the citizens of the EU, it must also be regulated to ensure that the emergence of AI does not negatively impact safety. In the medical field, in particular, EU patients must continue to benefit from the principle of risk minimization as AI becomes increasingly present in medical technologies.

Medtronic welcomes the use, in the proposed AI Regulation, of many concepts from EU harmonised legislation that are familiar to manufacturers of industrial products, including medical devices. This will help manufacturers and regulators to apply the requirements of the proposed AI Regulation in a way that is aligned with existing product safety legislation.

In this document, we will focus on the areas where the proposed AI Regulation will interplay with GDPR and MDR/IVDR and share recommendations that will help to avoid unnecessary complexity, overlaps or duplications.

Interface with GDPR

Medtronic recognises that the Commission's proposed approach seeks to integrate the proposed AI Regulation with existing EU legislation. In the case of GDPR, Medtronic is supportive of the approach by which the provisions of the GDPR, as a horizontal measure, will continue to apply to the processing of personal data, but subject to modification where required by the new proposal. In particular:

- We agree that, to enable achievement of the objective that bias monitoring and related measures should operate effectively, providers of high-risk AI systems will need to process certain special categories of personal data. Medtronic therefore welcomes and fully supports the proposal in Article 10(5) to overtly permit the processing of such data, to the extent strictly necessary and subject to the specified safeguards in order to facilitate achievement of the stated objective; and
- We recognise that the processing of personal data in the context of a new high-risk AI system is likely to require a data protection impact assessment under Article 35 GDPR. We note that under the AI Regulation users of high-risk AI systems are permitted to use the information provided under the transparency obligations contained in Article 13 of the proposed AI Regulation to comply with their obligation to carry out such an assessment (Article 29(6)). We further note, that if the information required to be taken into account in such a GDPR assessment is, for activities falling within scope of Title III of the proposed AI Regulation, limited to that required under Article 13 of the AI Regulation then that would be welcome in streamlining the requirements on businesses in respect of the collation of information relevant to the potential risks of processing. **We would welcome explicit confirmation in the AI Regulation that the information provided on the basis of Article 13 of the AI Regulation, is sufficient information in order to enable the assessment under Article 35 GDPR to be undertaken**.

Furthermore, our assessment highlights that there could be overlap between the proposed AI Regulation and GDPR in respect of **privacy and security by design**; and between the proposed AI Regulation and MDR/IVDR in respect of **risk management**.

Providers of high-risk AI systems will be dealing with three closely related regulatory dimensions. It appears that the result could be overlapping technical documentation for the AI Regulation and MDR/IVDR requirements and a GDPR DPIA and system design documentation for the purpose of the GDPR, which all need to be and remain consistent with each other over time.

We believe that such requirements, if not aligned, will be challenging for businesses to satisfy and encourages the European Commission, regulators and industry associations to coordinate proactively to ensure that clear guidance is put in place for businesses as to what is required and that compliance burdens are streamlined and minimised to the greatest extent possible in order to promote the development of AI.

Interface with MDR and IVDR

In this section, Medtronic will provide recommendations to help ensure that the proposed AI Regulation does not create unnecessary duplication of requirements for manufacturers of medical devices, which are already tightly regulated under MDR and IVDR. We will focus on two areas in particular:

1. The regulatory oversight and enforcement provisions of the AI Regulation risk creating a situation where there is overlapping competence for enforcement and provision of regulatory guidance in the medical device industry. This is very likely to lead to inefficiency and confusion, particularly where there are divergent interpretations.
2. In some instances, we have found that the proposed AI Regulation overlaps or conflicts with the already extensive and equivalent requirements under MDR/ IVDR.

We expand on these concerns further below and also provide suggestions for how these concerns can be addressed:

a. Overlapping regulatory authority competence both within the AI Regulation itself and with competent authorities under sectoral legislation

Medtronic agrees that enforcement and market surveillance by competent authorities that have expertise in the areas for which they have regulatory competence is appropriate. Nevertheless, we are concerned that national competent authorities, designated under the proposed AI Regulation could have overlapping competences with national authorities with competence under the vertical legislation for the product area concerned. This would increase regulatory complexity and require increased coordination among regulators and increased administrative workload to provide additional clarifications and guidance. It could also lead to inconsistent requirements from different regulators, which would be particularly problematic in areas where there is objective equivalence between the requirements in the AI Regulation and the relevant sectoral legislation.

Similarly, the multiplicity of national competent authorities specified in the AI Regulation and the fact that the AI Regulation assigns different roles to each of the national supervisory authority, market surveillance authority and the notifying authority risks resulting in "disconnects" amongst the authorities as each will operate within its own strict remit, thereby undermining the overall effectiveness of the regulatory system.

In the medical device sector, there are well-established competent authorities under MDR and IVDR. Furthermore, national competent authorities already employ an extensive regional market surveillance system and understand the environments in which medical devices are deployed. Those regulators are ideally placed to have sole competence for enforcement in relation to those products inclusive of any applicable requirements under the proposed AI Regulation.

We note in this regard that Article 63(3) of the AI Regulation already provides that the MDR and IVDR competent authorities shall be market surveillance authorities for the AI Regulation as regards medical devices.

Medtronic is supportive of that approach and recommends that the relevant competent authorities under MDR and IVDR have sole competence for regulating high-risk AI products within their sectoral remit, including any aspects of the proposed AI Regulation that may apply to those products. Such an

approach would make market surveillance more targeted and efficient, and would avoid potentially inconsistent approaches amongst co-regulators, making for greater legal certainty for users and providers of medical devices in the Union.

b. Recommendations to avoid overlap between proposed AI Regulation and equally stringent requirements under MDR/IVDR

The MDR already contains a robust, up-to-date regulatory framework for medical devices, including those enabled by AI. This includes ensuring appropriate performance of medical devices, taking into account their intended purpose, and also ensuring a high level of safety of medical devices. The MDR also places extensive obligations on manufacturers of medical devices regarding quality management, risk management, traceability and vigilance to monitor and assure the safety of a device throughout its lifecycle.

An important principle of the MDR is that manufacturers must continuously ensure a high level of protection of health and safety, taking into account the generally acknowledged state of the art. In the context of emerging technologies like AI, this ensures that manufacturers must always take into account the latest developments to ensure the safety of the product for users:

i. How the proposed AI Regulation handles risk of duplication

Whilst the AI Regulation states in Recital 85 that it amends the MDR and the IVDR, it is not entirely clear to see where the actual amendments are made. We appreciate that some measures are taken in the AI Regulation to avoid overlap, such as the option to provide a single set of technical documentation for the high-risk AI systems that are also devices within the meaning of the MDR and IVDR (Article 11(2) of the AI Regulation). However, in other areas there remains uncertainty.

We also note that Article 24 of the proposed AI Regulation includes a somewhat unusual overlap provision:

> *"Where a high-risk AI system related to products to which the [MDR or IVDR] apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider."*

This appears to us a kind of system / kit provision intended to manage exactly the cases caught under the systems and kit provisions already provided for under the MDR and IVDR and is therefore unnecessarily duplicative and a potential source of confusion. We therefore suggest this be disapplied for medical devices.

ii. Avoiding parallel conformity assessments and the need for more than one notified body

Article 43(3) of the AI Regulation appears to be an attempt to manage the overlap in relation to conformity assessment, providing that AI systems, that are devices or are part of a device, can be assessed under the MDR or IVDR conformity assessment procedure (albeit with some additional requirements). This raises the following questions:

- How will that work with notified bodies?

- Do they need accreditation under the AI Regulation as well to do a full MDR or IVDR AI system/ device assessment?
- Under what MDR / IVDR code would that notified body competence be covered?
- Would it be possible to split the device / AI system by having the AI part evaluated by an AI Regulation notified body and the device part by an MDR / IVDR notified body?

We welcome the provisions at Article 43(3) of the AI Regulation confirming that MDR/IVDR notified bodies may in principle also perform conformity assessment of aspects of devices covered by the AI Regulation. Nonetheless, in light of recent experience under the MDR / IVDR where many manufacturers have been left without a designated notified body, Medtronic is very concerned that there will be insufficient notified bodies designated for both the MDR/IVDR and also the proposed AI Regulation. This will result in providers/manufacturers having to appoint two notified bodies (one for the MDR / IVDR aspects and a separate body for the AI Regulation aspects. This would add significant complexity to the conformity assessment process for manufacturers / providers and may also result in divergent assessments by notified bodies unless care is taken to recognise equivalence in relation to the requirements of Chapter 2 of Title III of the AI Regulation to avoid overlapping assessments.

iii. *Need for clarity around the overall declaration of conformity*

The AI Regulation does not address how the result of conformity assessment from both regimes (i.e. MDR / IVDR and the AI Regulation) will be reflected in a final declaration of conformity. The result under the AI Regulation appears to be an EU technical documentation certificate (Article 44 of the AI Regulation) which seems to be complementary to an MDR / IVDR certificate and, according to the MDR / IVDR, might be accounted for in a single declaration of conformity for the AI system under both regulations (AI Regulation and the MDR or IVDR, as applicable).

Equivalence between MDR / IVDR and the requirements of Chapters 2 and 3 of Title III

Certain provisions contained in the proposed AI regulation overlap with the equally stringent requirements in the MDR. Therefore, Medtronic recommends that the proposed AI Regulation provides for a mechanism where medical device manufacturers that comply with equivalent and equally stringent provisions contained in the medical devices sectoral legislation would be expressly deemed to also comply with the requirements of Chapters 2 and 3 of Title III of the proposed AI Regulation. We have set out our specific proposals for this in the bulleted points below:

- **The MDR sets out stringent risk management and mitigation requirements equivalent to those in the AI Regulation.**

  It is a fundamental principle of the MDR that device risks must be acceptable in light of the benefits of the product. Manufacturers must demonstrate this acceptable benefit-risk balance prior to placing the product on the market and must constantly monitor the risk. The extensive risk management and mitigation measures that must be implemented by manufacturers before placing a device on the market and in the post-marketing phase are therefore fundamental to ensuring the safety and performance of medical devices under the MDR and IVDR. These are largely contained in the general safety and performance requirements in Chapter I of Annex I of

the MDR. These are similarly worded and substantively equivalent to the risk management system provisions contained in Article 9 of the proposed AI Regulation. The result is that Article 9 of the AI Regulation will create duplication and lead to uncertainty. The risk control measures adopted by the manufacturer must also conform to the generally acknowledged state of the art so these will inevitably include anything specific to the AI context.

On this basis, we consider that wording should be included in Article 9 of the AI Regulation that manufacturers of medical devices are deemed to have complied with the requirements of Article 9 of the AI Regulation by complying with the relevant risk management provisions of the MDR. This will help avoid the risks of regulators and notified bodies coming to differing interpretations on the requirements of these provisions and whether there has been compliance by providers and manufacturers under the horizontal AI Regulation and the vertical MDR / IVDR.

- The MDR includes detailed requirements on providing adequate information to users of devices.

  MDR places extensive requirements on manufacturers to provide information to users including instructions for use, information regarding the manufacturer and information on risks as well as any limits on accuracy in the case of devices with a diagnostic or measuring function. Under those provisions, device manufacturers must reduce risks as far as possible and provide information for the safety of users and, where appropriate, provide training. Further, manufacturers must inform users of any residual risks. Consequently, the provision of information requirements contained in Article 12 of the proposed AI Regulation serve only to duplicate existing requirements for medical device manufacturers who are also providers of high-risk AI systems. We therefore propose that wording be included in Article 13 of the proposed AI Regulation to the effect that medical device manufacturers will be deemed to comply with the requirements of Article 13 of the AI Regulation where they comply with the relevant provisions of the MDR/IVDR, namely the information requirements set out in Annex I.

- The MDR includes provisions enabling transparency and human oversight of devices.

  The principles of ensuring appropriate transparency and enabling human users to have appropriate oversight of devices and their outputs are already found in the MDR. Specifically, the MDR/ IVDR require that devices for self-testing / use by lay persons, where appropriate, enable the user to verify that the device will perform as intended by the manufacturer and/or that the user be warned if the device has failed to provide a valid result. Additionally, the labelling and instructions for use requirements each require residual risks to be communicated to the user or other person as limitations, contra-indications, precautions or warnings. As such, we believe requirements broadly equivalent to those contained in Article 13(1) and 14 of the proposed AI Regulation are already found in the EU medical devices legislation.

  Therefore, we believe that medical device manufacturers complying with the relevant medical devices legislation should be expressly deemed to also comply with the requirements of Articles 13(1) and 14 of the proposed AI Regulation.

  Alternatively, if it is considered desirable for device labelling or instructions for use to specifically identify the matters set out at Article 14(2) of the draft AI Regulation these could easily be included by way of an amendment to section 23 of Annex I MDR and section 20 of Annex I IVDR.

- **The MDR and IVDR ensure high levels of accuracy and robustness.**

  Under the MDR devices that have a diagnostic or measuring function must be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose based on appropriate scientific and technical methods. Further, the MDR applies specific requirements to software medical devices to be developed in accordance with the state of the art and to be designed to ensure appropriate repeatability, reliability and performance in line with their intended use. On this basis, we consider that the requirements relating to accuracy and robustness in Article 15 of the proposed AI Regulation constitute an unnecessary duplication of the requirements in the MDR and risk creating legal uncertainty.

  We therefore consider the best approach would be to include wording similar to that proposed above, namely that medical device manufacturers that comply with the relevant parts of Annex I of the MDR shall be deemed to comply with the requirements relating to accuracy and robustness under Article 15 of the proposed AI Regulation.

- **The MDR together with associated guidance from the Medical Devices Coordination Group (MDCG) ensures high standards of cybersecurity for software medical devices including those involving AI.**

  The MDR requires that software medical devices must be designed in accordance with the state of the art and this includes taking into account the principles of development life cycle, risk management, including information security, verification and validation. To complement the statutory requirements, the Commission has issued guidance endorsed by the MDCG which reinforces these requirements and sets out practical steps for manufacturers to ensure appropriate cybersecurity specifically in the medical devices context. On top of these requirements, the MDR explicitly requires all device manufacturers to comply with the requirements of the GDPR. Taken together, these requirements already demand high standards of cybersecurity from medical device manufacturers. Requiring device manufacturers to comply with the cybersecurity requirements in Article 15 of the AI Regulation would simply serve to duplicate requirements and create uncertainty when there is already a device-specific regime addressing these risks to state of the art. Having parallel requirements will predictably lead to confusion between the application of the horizontal and vertical legislation in this area.

  We therefore consider that the specific sectoral requirements should take precedence and medical device manufacturers that comply with the relevant sections of the MDR (including the guidance from the MDCG) should be deemed to comply with the requirements on cybersecurity in Article 15 of the proposed AI Regulation.

- **The MDR imposes detailed obligations on manufacturers of medical devices.**

  The MDR places primary responsibility for the safety, quality and performance on manufacturers of devices, who will be providers of high-risk AI systems under the AI Regulation. As such, it sets out wide-ranging obligations on manufacturers including undertaking the relevant pre-market conformity assessment, drawing up detailed technical documentation, vigilance and post-market surveillance and post-market clinical follow-up, implementing a quality management

system, communicating with competent authorities and undertaking corrective and preventive actions. These are in our view equivalent and in many cases more detailed and stringent than the requirements contained in Chapter 3 of Title III of the proposed AI Regulation. For example, the MDR sets out detailed requirements for the implementation of a quality management system by medical device manufacturers which, in conjunction with the recognised global technical standard for medical devices quality management systems (ISO EN 13485), sets high standards for quality management systems for medical device manufacturers.

To avoid unnecessary and costly duplication and potential legal uncertainty we believe that medical device manufacturers should be deemed to comply with each of the requirements of Articles 16, 17, 18, 19, 21, 22, 23 and 25 of the AI Regulation where they comply with the equivalent requirements of the MDR and that express wording to this effect should therefore be included in the proposed AI Regulation.