MEDTRONIC SUBMISSION ON ARTIFICIAL INTELLIGENCE

Mr. Kilian Gross,
Head of Unit,
Technologies and Systems for Digitising Industry,
DG CONNECT,
European Commission.

Dear Mr. Gross,

On behalf of Medtronic, we welcome the Commission's invitation to share our views and perspectives on the *EU White Paper on Artificial Intelligence*.

Medtronic is a medical technology leader headquartered in Ireland, employing more than 90,000 people worldwide, and offering therapies and solutions that enable greater efficiency, access, and value for healthcare systems, providers, and the patients they serve. Making healthcare better is our priority, and we believe medical technology can play an even greater role in improving people's lives.

Innovation and collaboration are central to who we are. Since the late 1940s, we have been working with others to alleviate pain, restore health, and extend life. Today, our therapies improve the lives of more than two people every second. Many stakeholders may know us as the company that invented the first batter-powered portable pacemaker, the diabetes pump maker, or the company that open-sourced ventilator design to respond to the COVID-19 pandemic. We do so much more. As the world's largest medical technology company, we create innovations at the therapeutic, procedural, and system level.

Our Mission: innovation with responsibility.

In 1960, our founder, the late Earl Bakken, wrote the Medtronic Mission. Since then, our Mission has reminded us that our foremost priority is to contribute to human welfare and it has provided an ethical framework and inspirational goal for Medtronic employees around the world. The third Tenet of the Medtronic Mission states:

> *"To **strive without reserve for the greatest possible reliability and quality** in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service."*

We are proud of Medtronic's history of partnering with healthcare professionals to bring staggering technological advancement into everyday accessible healthcare. It's our deep pedigree of innovation for good – grounded by our founders' paramount ethical commitment – that prompts us to share our thoughts and comments on the Commission's *White Paper on Artificial Intelligence*.

Importance of artificial intelligence (AI) for Medtronic.

AI is sweeping through healthcare. It has already found many applications in the field of hospital operations like patient triaging or the streamlining of repetitive tasks. Over the next few years, we will also see a new generation of AI-enabled medical devices come to market. The most-promising benefits of those technologies are better clinical decision-making, faster and more accurate diagnoses, more targeted therapies and more personalised care. Those new technologies will significantly improve patient health

outcomes and provide cost-savings and efficiency gains to healthcare systems. Developing AI functionalities is therefore a key priority in the two billion euros of research we invest in R&D every year in the EU and across the world.

Need for equivalence, not new regulation.

Medtronic welcomes the Commission's plans to (i) pursue a uniform approach to AI across the EU to avoid divergent Member State requirements and barriers to its single market; and to (ii) take a risk-based, sector-specific approach to regulating AI.

However, we have concerns with the Commission's viewpoint that the already high ethical and regulatory standards for the medical devices industry may be increased further merely because our innovative products and therapies might utilise AI. Instead we believe that the regulatory standards to which Medtronic and its competitors in the medical device industry are already held are equivalent, if not higher, than those being suggested in the White Paper.

As we will outline in this letter a *doctrine of equivalence* should be the solution for the Commission's concerns. If sectoral regulation already meets or exceeds the minimums required by an AI regulation, then those regulated should not be required to spend time and energy on horizontal AI-regulation *in addition* to their existing sectoral regulation. This doctrine of equivalence provides advantages not only to regulated entities, but is also for the benefit of healthcare professionals, patients, Member States as well as sectoral and AI regulators.

We will explain these advantages – and the risks of arbitrage and "regulator shopping" if two regulations apply to one service.

Avoiding uncertainty, duplication and arbitrage risk.

Whatever the legislative outcome from the Commission's AI White Paper, it is highly likely that any horizontal AI regulation will differ and possibly conflict in certain regards from the existing and future sectoral frameworks under which medical devices companies operate. The Commission has a constitutional precedence challenge of how to deconflict these two regimes to avoid uncertainty, duplication and risk.

One option is to expressly legislate that the new AI regime will run in parallel with the sectoral regime, or in other words, a specified law shall always prevail. Another option is to simply leave the resolution to the principle of *lex specialis*, where any general regime is trumped by anything more specific. We would strongly caution against these approaches which undermine legal certainty. The Commission will have seen the many CJEU cases that need to resolve which law is *lex specialis* and then, whether the issue before the court falls within the overlapping domain.

If there is a way to regulate medical products which incorporate AI, it's clearly better that those regulations are written once rather than twice. Overlapping regulations will likely slow down the release to market of life-saving products. Conflicting regulations may likely lead to a decrease in compliance as it may be unclear which regulation prevails. Moreover, two sets of regulations – unless identical – will very likely lead to arbitrage by some because of the risk and benefit of differing interpretations of the same set of facts. Companies accused by one regulator of being in breach of one regulation, might hold up their supposed 'compliance' with the other regulation as a moral if not legal defence. If two laws apply, it is foreseeable that non-medical device companies will position and market their AI-enabled products for utilisation in healthcare outside the scope of more onerous regulation such as the EU Medical Devices Regulation.

Two sets of regulations, by definition, point to duplication of effort from both the Commission and the Parliament as well as, when it comes to supervision and enforcement, competent authorities and enforcement agencies. All the time, any "AI" regulators in Member States or at an EU level will need to

liaise with their equivalent sectoral counterparts (such as the EU Medical Devices Coordination Group) to ensure a combined, coordinated and coherent approach to a particular issue or entity.

Where there is equivalence.

Medtronic is respectful and fully supportive of the need for its medical device products utilising AI to be subject to an appropriate level of supervision, oversight and regulation. We agree that the citizens of Europe need to be confident that their medical devices, with or without an AI component, provide a high level of safety and quality for patients. It is precisely for this reason that the Medical Device Regulation (MDR) provides a high level of protection of health for patients and users, whilst taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns for such products. Both objectives are being pursued simultaneously and are inseparably linked with one not being secondary to the other. For these reasons, Medtronic does not agree that the use of any type of AI in the health care sector poses an additional high risk that requires separate horizontal regulation. Rather, Medtronic believes that principles-based Guidance from the Medical Devices Coordination Group is most appropriate to identify and address AI's specific characteristics within the existing sectoral regulatory framework of the MDR.

The medical technology sector has a long history of continuous evolution, with new types of technology being incorporated into devices. As these new types of technology have come forward, medical device regulators have developed specific new standards and requirements to properly analyse risks and evaluate safety. Medical device regulatory practice is founded on the expectation of this continued evolution of break-through and innovative new technology. The advent of increased use of AI in medical devices is not out of the ordinary, in terms of both the need and the capability of regulators to analyse the risks and develop the standards and requirements to properly evaluate the risks and ensure patient safety.

For example, more than a decade ago, implantable cardiac rhythm devices acquired the ability to monitor heart rhythm and transmit electronic reports of a patient's heart conditions from the patient's home to a physician via a bedside modem. Medical device regulators have continuously demonstrate a proven ability to adapt and develop regulatory requirements for such wholly new capabilities for traditional cardiac rhythm devices.

To illustrate this existing equivalent protection, we have set out some of the key issues that the White Paper suggests are important for AI regulation and then mapped these across the existing Medical Devices Regulation.

We do this for two reasons. First, we hope that this shows that those in our regulated medical device sector will be meeting these high standards, with or without AI. Second, we expect this mapping will reveal to the Commission that the high risks they sought to control through the AI regulation are *already* regulated by medical device regulators across the EU. And so, even if the Commission remains minded to re-regulate in these areas in relation to companies like Medtronic, it will need to determine which body would resolve conflicts between the two regimes.

EU Medical Devices Regulation: a 'toolbox' for future regulation of AI.

The Commission identifies the main concerns associated with AI, IoT and robotics are the adequate protection of fundamental rights and safety. The Parliament's IMCO rapporteur has identified that approximately one third of all products currently in circulation in the single market are not regulated on a harmonised basis. In contrast, the medical devices sector is one of the most intensively regulated harmonised product sectors. It is also subject to a highly coordinated governance framework led by the Commission and the Medical Device Coordination Group (MDCG) comprising Member State designees with competence and technical expertise in the field of medical devices to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised

implementation of the MDR and the updating of this in light of technical progress. The MDCG is tasked amongst other matters with:

- contributing to the joint assessment of conformity assessment bodies (Notified Bodies);
- contributing to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements for medical devices are adequate to ensure safety and performance of devices, and thereby contributing to identifying whether there is a need to amend the MDR;
- contributing to the development of device standards, common specifications and scientific guidelines, including but not limited to clinical trials of certain devices;
- assisting the Member States in their coordination activities in particular in the fields of clinical trials, post-market safety reporting (vigilance) and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance; and
- providing advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of the MDR.

A sectoral approach is essential for building trustworthy AI.

A horizontal approach to regulating all AI applications will be counterproductive. In this regard Medtronic strongly agrees with the High-Level Expert Group on AI, that different situations raise different challenges and a sectoral approach is necessary given the context-specificity of AI. The MDR sets out a detailed, technical and ethical regulatory framework specifically addressed to the safety and performance, as well as ethical, risks presented by medical devices. This includes the Helsinki Declaration[1] ensuring medical research is subject to ethical standards that promote and ensure respect for all human research participants and protect their health and rights. If needed, the Commission has secondary legislative powers available to adapt this framework in order to address technological progress.

The MDR requirements already address the types of requirements for AI regulation outlined in the White Paper. MDCG guidance and/or or harmonised standards (or even possibly secondary legislation, if necessary) can also be used to adapt these to meet technical developments to establish 'state of the art', if appropriate]. Within this technical and ethical regulatory framework the MDR already contains comprehensive provisions addressing the regulatory gaps and/or the future requirements for AI regulation which the White Paper identifies. For example:

1. **MDR's calibrated risk classification of devices ensures proportionate pre-market conformity assessment against detailed technical and ethical requirements including independent expert scrutiny**. The MDR's 4-tier, risk-driven classification system for medical devices ensures intensified independent pre-market expert scrutiny of higher risk devices (coordinated by the Commission, the MDCG and expert sub-groups) based on the Notified Body's evaluation of the manufacturer's prescribed, detailed pre-market technical documentation and clinical evaluation and trial data for the devices in question. The risk classification system is calibrated to allow for oversight by Notified Bodies, or by the manufacturer itself, for lower risk devices thereby ensuring an overall proportionate approach to pre-market conformity assessment of medical devices, without fettering innovation or unduly burdening companies, including SMEs. As the classification system allows for up- or down-classification of groups of devices by the Commission (in consultation with the MDCG) based on public health grounds or in light of new scientific evidence or post-market safety and performance information the risk classification system is able to remain fit for purpose and adaptive to new risks arising from technological progress and innovation.

2. **MDR's detailed 'safety' concept already addresses potential cyber-vulnerability.** The MDR's broad 'safety' concept already explicitly covers key aspects of the emergence of digital

[1] World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

technologies, e.g. security, complexity of systems, software as a separate product and connectivity. All activity regulated by the MDR is also required to comply with GDPR requirements. Indeed, MDCG is already issuing Guidance in this area to reinforce and set out the practical steps needed to meet the MDR's 'safety' requirements.

The MDCG acknowledges that the MDR enhances the focus of legislators on ensuring that devices placed on the EU market are fit for the new technological challenges linked to cybersecurity risks. MDCG points out[2] that the MDR lays down specific essential safety requirements for all medical devices that incorporate electronic programmable systems and for software that is a medical device in itself. These require manufacturers to develop and manufacture their products in accordance with the state of the art taking into account the principles of risk management, including information security, as well as to setting out minimum requirements concerning IT security measures, including protection against unauthorised access. MDCG also specifies reporting codes to be used by manufacturers for cybersecurity incidents associated with medical devices.

3. **All pre-market design and manufacture is subject to risk control measures. Devices must be accompanied by prescribed safety and performance data detailing intended uses and limitations.** All devices must be designed and produced so that all residual risks which cannot be eliminated via the design process are judged acceptable and mitigated via alarm / alert functionality and by prescribed, comprehensive product information provided to users explaining the device's functionality and also its limitations. Higher risk devices must also be accompanied by a public summary of the device's safety and clinical performance to make clear to the intended user (whether a healthcare professional or a patient) the device's intended purpose, to provide information on risks, undesirable effects, warnings and precautions and to summarise the pre-market and post-market clinical experience of the product.

4. **Traceability and transparency are assured through detailed technical documentation and retention obligations.** Device design and manufacturing processes are each subject to detailed technical documentation requirements which allow the design stages applied to an individual device to be understood and all sites and suppliers or subcontractors to be identified. This detailed documentation, which must be retained for a specified time after the lifetime of the device model, must include the manufacturer's benefit-risk analysis for the product; the risk management solutions adopted to design, manufacture, monitor and manage risk throughout the product's lifecycle; the validation and verification testing conducted and the pre-clinical and clinical trial data including in particular data for any software verification and validation as well as data on performance and safety in clinical use. Over time the post-market clinical-follow-up, safety and performance data (including periodic safety update reports) for the device are added to the technical documentation so the technical file keeps pace with the device throughout its lifecycle.

5. **Risk management extends throughout a device's lifecycle from design through proactive post-market clinical follow-up, safety reporting (vigilance) and corrective interventions.** Medical devices manufacturers must operate a risk management system and plan for each individual device which must not only identify and analyse the known and foreseeable hazards associated with each device but must also estimate and evaluate risks occurring during the intended use (or foreseeable misuse) of the device. Design must accordingly be for patient safety but must also be for the intended lay, professional, disabled or other users and therefore take account of users' technical knowledge, experience, education, training and use environments. Adverse safety or performance data received during the post-market life of a device must be evaluated for reporting to Member State authorities. Manufacturers of all but the lowest risk class medical devices must also file periodic safety update reports summarising the results and conclusions of the analysis of the post-market safety and performance data with a rationale and description of any preventive and corrective actions taken throughout the lifetime of the device.

[2] MDCG 2019-16 (December 2019): *Guidance on cybersecurity for medical devices*

'Placing on the market' is by no means the end of the manufacturer's accountability for the safety and performance of the device. As part of their post-market obligations to collect and evaluate device safety and performance data from the field over the life of a medical device, manufacturers must operate a post-market surveillance plan for each product and proactively update their clinical evaluation of the safety and performance of the product through planned post-market clinical follow-up, for example via collection of data in clinical registries, case studies or post-market studies. Adverse safety or performance data must be evaluated for vigilance reporting to Member State authorities, including via periodic safety update reports. The aim of these processes is to confirm the safety and performance throughout the expected lifetime of the device in question, to ensure the continued acceptability of the identified risks and to detect emerging risks on the basis of factual evidence while ensuring appropriate corrective actions are instituted on a timely and transparent basis, where needed. Devices, whether enabled with autonomous AI or not, will thus be subject to proactive ongoing post-market clinical follow-up, post-market surveillance and continuous monitoring and (re-)evaluation of their benefit-risk profile, also where products are subject to updates or user uploads over their expected lifetimes. Member States, the Commission and the MDCG will each maintain a transparent overview of device performance and safety through the vigilance process.

Cooperation and accountability throughout the supply chain. All economic operators involved in the downstream supply and use of devices have legal obligations to record the source and supply of the devices they market and also to monitor, record and cooperate with each other, with the manufacturer and with competent medical device authorities with regards to the conformity and safety of medical devices in the post-market phase. Not just the manufacturer but also other economic operators have obligations to report serious risks associated with medical devices they supply to the medical device authorities (vigilance) and to provide them with all the information and documentation necessary to demonstrate the conformity of the device where requested. All economic operators involved are therefore accountable for the monitoring and ongoing evaluation of a device's safety and performance and for ensuring timely corrective actions are taken, where needed.

6. **Post-market modifications trigger re-assessments of conformity.** Where devices undergo modification after marketing by a third party, or their intended uses are changed, the MDR treats such changed products as completely new medical devices, requiring completely fresh conformity assessments to be undertaken by the modifier before they may make available or put into service such changed devices. Similarly, where an original manufacturer makes substantial changes to its own device or to its quality management system, MDR requires a re-assessment of the changed product or quality system by the Notified Body and for all changes to be captured in the manufacturer's technical documentation for the product.

Regulation not duplication.

We hope that this letter demonstrates Medtronic's full support for regulation of its devices, whether or not they utilise AI. Our commitment to quality is first and foremost rooted in patient safety. When employees and our partners uphold a culture of quality and put the patient first, we can successfully execute on processes and protocols that ensure quality, reliability, and regulatory compliance — from development and manufacturing to distribution and patient use.

We have shown in the mapping exercise above, and look forward to providing deeper analysis, that AI-innovations in medical devices will be effectively regulated by the EU Medical Devices legislation. We trust that this allows the Commission to consider that creating special rules for healthcare within any AI-regime will be duplicative of the great and important work already done by DG Internal Market and DG Santé.

Instead, we would urge the Commission to look to a doctrine of equivalence whereby if there is already equivalent (or often higher) principle elsewhere, meeting that will satisfy any AI-specific rules.

At Medtronic, we are committed to transforming healthcare, but we know we can't do it alone. As global healthcare evolves, it is our responsibility as partners to evolve with it. We see great opportunities ahead to help more patients, in more places, around the world. Getting there will take working with others who share a steadfast commitment to data transparency and integrity, use of technology and a focus on patient outcomes.

Next steps.

We have appreciated the opportunity to share our views on this consultation directly to the Commission and through MedTech Europe's submission on behalf of industry. We contributed to this and we support its comments and recommendations on the technical and sector-specific issues we have not addressed in this letter.

Medtronic are fully committed to supporting the work of the EU institutions in this area and will, over the coming months, provide the Commission with a deeper written analysis with real-world examples to illustrate our thinking. Following this, we look forward to arranging a meeting to discuss this further with you and your team shortly – whether in person or remotely.

Kind regards,

John Brennan
Vice President EMEA,
Regulatory, Quality and Government Affairs

Charity Kufaas
Vice President EMEA,
Strategy and Business Development