HOOGHIEMSTRA & PARTNERS
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AXON science based lawyers

Legal analysis

European legislative proposal draft AI act and MDR/IVDR

Wimmy Choi, Marlies van Eck, Cécile van der Heijden, Theo Hooghiemstra & Erik Vollebregt

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1. Introduction

1.1 Intro

In April 2021, the European Commission (EC) published a proposal for a regulation of European Parliament and the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union legislative acts COM (2021) 206. In this report we will refer to this proposal as the "draft AI Act" or "AIA".

The Ministry of Health, Welfare and Sport commissioned Hooghiemstra & Partners and Axon Lawyers to investigate and analyse the relation between the draft AI Act and already existing European regulatory measures in health care. More specifically the Ministry wants to know how compatible the draft AI Act is with Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices (hereafter: "MDR") and Regulation (EU) 2017/746 of the European Parliament and the Council of 5 April 2017 on in vitro diagnostic medical devices (hereafter: "IVDR"). Considering the general character of the draft AI Act and its aim to regulate a variety of practices in several legal areas, it can't be excluded upfront that the proposal may have some overlap or inconsistencies with the two aforementioned regulations.

As harmonising of rules is one of the goals of the draft AI Act, the MDR and IVDR are included in Annex II of the AI Act, more specifically in the list of Union Harmonisation Legislation, section A of the aforementioned annex. This means that the legislator aims to harmonise the legal framework.

Medical devices that are AI-systems or consist of AI-systems as defined in article 3, under 1, draft AI Act fall under the scope of the draft AI Act.[1] This means that additional rules apply to the medical devices containing artificial intelligence from the draft AI Act on top of the requirements in the MDR and the IVDR. The Ministry has informed the authors of this report that it is currently unclear to the Ministry what the impact of this overlap between the various regulations will be.

1.2 The assignment

The following questions will be answered in this report:

- Which articles in the draft AI Act can be applied to medical devices or other digital health systems?
- What is the possible overlap between the draft AI Act and the MDR and IVDR?
- What are the potential conflicts between the draft AI Act and the MDR and IVDR?
- What are the possible consequences?

Lastly, we will come to an advice on concrete amendments to the articles and provisions of the draft AI Act.

In order to answer the above-mentioned questions, we first need to investigate the scope of the draft AI Act, its legal foundation and relation with the already existing national legal framework.

1.3 The Draft AI Act

Many citizens, companies and governments have found the many benefits of AI and are using it on a daily basis. It is expected that the use of AI will only increase over the years. According to the EC, AI is a fast-evolving family of technologies that can bring many benefits across the entire spectrum of industries and social activities.

[1] Annex II, rule 11 and 12 draft AI Act.

The ability to improve predictions, optimise existing processes and personalise the service or product, can support socially and environmentally beneficial outcomes and provide key competitive advantages to companies and the European economy. However, AI can also bring new risk or negative consequences for individuals or the society. Therefore, the EC considers it necessary for automated systems to be regulated at the European level so that Europeans can benefit from new technologies developed and functioning according to Union values, fundamental rights and principles.

The EC has four specific objectives in mind when drafting the AI Act:

- ensure that AI systems placed on the Union market and used are safe and respect existing law on fundamental rights and Union values;
- ensure legal certainty to facilitate investment and innovation in AI;
- enhance governance and effective enforcement of existing law on fundamental rights and safety requirements applicable to AI systems;
- facilitate the development of a single market for lawful, safe and trustworthy AI applications and prevent market fragmentation.

The legal instrument that is chosen is a risk based approached taking the technology -instead of the legal spheres they are used in as the starting point. As a consequence, the draft AI Act is very general and extremely broad, and not specifically written written for the use of AI i n health care. We believe this approach has several down sides for our national health care organisation. In the following we will navigate to this conclusion based on insights of scientists and a brief description of a few aspects of the legal framework of health care in the Netherlands.

1.4 Scientists on the draft AI Act

Although a lot is still uncertain, we will bring to the attention four expert analysis. In short, these researchers point out four important views:

1. The draft AI Act doesn't contain the right instrument to regulate AI. It reduces the legal regulation of the use of AI to a formal procedure of ticking boxes and fulfilling administrative requirements. Van der Linden writes the focus instead should be shifted to application and enforcement of existing law.[2]
2. the draft AI Act risks an extraordinarily broad scope, with the supremacy of European Law restricting legitimate national attempts to manage social impacts of AI systems' use in the name of free trade. Vaele and Zuiderveen Borgesius conclude that the proposal may even disapply existing national digital fundamental rights protection or restrict future national regulation.[3]
3. the proposal leads to uncertainty for developing medical robots because full compliance with the regulation is at present beyond the state of the art. The selective pressure induced by differentials in the regulatory burden could result in changes at the organizational level, mirroring changes in problem decomposition and formulation. Fiazza warns that in response to liability pressure, research entities active in medical robotics may turn to a 'dual track' strategy for their (native) research questions, especially concerning technologies whose accurate evaluation is strongly dependent on large numbers and which may thus require market deployment of prototype technology. Perhaps as a result of the approval of the

[2] T. van der Linden, 'Regulating Artificial Intelligence: please apply existing regulation'. Amsterdam Law Forum, 2021 < https://amsterdamlawforum.org/articles/abstract/432/ >

[3] M. Veale & F. Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act' *Computer Law Review International* (2021) 22(4) 97-112 via SSRN: https://ssrn.com/abstract=3896852

framework, market deployment in nonregulated fields of application will spearhead the availability of innovative solutions for the medical and surgical settings. [4]

4. In November 2021, the Netherlands Scientific Council for Government Policy ("WRR") published her extensive research report on AI. The Council concludes that it's extremely important that the Dutch Government has an AI Strategy and chooses how to regulate the use of AI. The Council mentions a key question that resembles discussions in the past on the regulation of personal data protection Once regulation is needed: does it need to be general, i.e. by a so called 'omnibus law', or should it be regulated in specific sectoral legislation? As the WRR states, it would seem sensible to choose a generic regulation in light of the broad applicability of AI. However, the issues relating to AI, such as the need for transparency or explainability, show that specific knowledge of both the context and goals involved in the area of application is required. "*For example, explainability in healthcare requires different things than in consumer-based applications or environmental safety. Consequently, the right balance between generic and specific regulation thus needs to be struck in such a way that considers the protection of public values, while, simultaneously, leaving space for innovation*."[5] The WRR advises the Dutch government to explicitly consider the kind of regulation that is needed and chosen; omnibus or domain specific. [6]

1.5 National legal framework in Health Care

Next to hereafter answered questions regarding the relation between the draft AI Act and MDR/IVD, another important issue is the relation of the draft AI Act with Member States national legal frameworks. In The Netherlands, patients' rights and professional standards for doctors and other health care professionals play an important role. Seeking adequate treatment is considered to be the result of a dialogue between professional and patient. The relation between the healthcare provider and the patient is governed by the provisions of the Medical Treatment Agreement Act (Wet op de geneeskundige behandelingsovereenkomst, "WGBO"), the Healthcare Quality, Complaints and Disputes Act (Wet kwaliteit, klachten en geschillen zorg, "Wkkgz") and part of the Dutch Civil Code.

According to the Wkkgz, the health care provider must provide proper care to the patient. This implies that the health care must be of good quality and of a good level, which is at least safe, effective, efficient and client-orientated, is provided in a timely manner and is aligned with the real needs to the patients. The health care provider must also act in accordance with their responsibilities arising from the professional standards and the quality standards. The rights of the patient must also be carefully observed by the healthcare provider and the patient must be treated with respect. One of the patient's rights is the medical professional secrecy. It is an important part of the relationship between the healthcare provider and the patient. Medical professional secrecy means that – in principle – individual healthcare providers may not disclose information about their patients to third parties. In other words: medical healthcare providers have a duty of silence regarding the information about their patients to third parties. In the Dutch health legislation, professional secrecy can be found in the Health Care Professions Act (Wet beroepen individuele gezondheidszorg, "Wet BIG") and the Medical Treatment Agreement Act. The WGBO focuses on the contractual relationship between patient and health care provider with expectations regarding confidentiality and professional secrecy.[7]

[4] M. Fiazza, 'The EU Proposal for Regulating AI: Foreseeable Impact on Medical Robotics', 2022 IEhttps://iris.univr.it/retrieve/handle/11562/1052855/220262/IRIS_EURegulation_AI.pdf
[5] WRR, Mission AI. The New System Technology. Summary, 2021. < https://www.wrr.nl/publicaties/rapporten/2021/11/11/opgave-ai-de-nieuwe-systeemtechnologie >
[6] WRR, Opgave AI. De nieuwe systeemtechnologie,2021, p.304.
[7] T. Hooghiemstra, Informational self-determination in healthcare, Tilburg University 2018, p. 65.

If there is a dispute between the healthcare provider and the patient, the patient has several choices to make in order to obtain justice.

The patient can choose to file a complaint against the healthcare provider. If the patient is not satisfied with the response to that complaint, he can submit the dispute to the Disputes Committee. The patient cannot appeal if he does not agree with the decision of the Disputes Committee. If the patient is not satisfied with the decision from the Disputes Committee, the patient can request the court to undo the decision. The patient can also go to the civil court or the disciplinary court immediately after the dispute has occurred. In rare cases, a healthcare provider is summoned to the criminal court by the public prosecutor's office if the healthcare provider might have committed a criminal offense. The patient may appeal against the decisions of the court in the first instance. Healthcare providers are supervised by the Health and Youth care inspectorate.

2 MDR and IVDR

2.1 Intro

A device in scope of the MDR or IVDR that also qualifies as an AI system under the draft AI Act will need to meet obligations both under the MDR or IVDR and the draft AI Act.[8] This is the case because it follows from Article 6 draft AI Act that the draft AI Act qualifies all such devices as high-risk AI systems. As a result, and as this legal analysis will show hereinafter, there is a large overlap of regulation between the MDR/IVDR and the draft AI Act.

If an AI system qualifies as a device under the MDR or IVDR, meeting the obligations under the draft AI Act also comprises a conformity assessment in accordance with the MDR or IVDR, with additional requirements under the draft AI Act included in the conformity assessment pursuant to article 43(5) draft AI Act. In practice this means that the notified body conducting the conformity assessment under the MDR or IVDR will also conduct this conformity assessment.

2.2 New legislative framework

AI systems qualifying as medical devices have been effectively regulated under the predecessors of the MDR and IVDR for years.[9] AI-systems qualifying as medical devices have been CE marked under the MDD as class I self-certified devices or class Iia / Iib active diagnostic devices and under the IVDD as self-certified software devices or as list II notified body certified devices. The successive regulations, the MDR and the IVDR, are so-called New Legislative Framework (NLF) regulations which were built on the same regulatory template for CE-marking regulations (based on Regulation (EU) 768/2008). The successive regulations, the MDR and the IVDR, are so-called New Legislative Framework ("NLF") regulations which were built on the same regulatory template for CE-marking regulations (based on Regulation (EU) 768/2008). The NLF legal acts are built on the legal concept that the more specific regulation for a given product will take precedence in providing the regulatory framework for that product, while more specific health and safety requirements of the horizontal legislation need to be met under the more specific legislation.[10] This has been implemented in the MDR and IVDR in the relation to CE marking regulations and directives to which the devices currently qualifying under the MDR and IVDR would have to conform if they did not have a medical intended purpose.[11] By means of the concept that the more product specific regulation applies, but more specific health and safety requirements must be met under horizontal legislation, it is ensured that devices under the MDR and IVDR are not subjected to a double regulatory burden. It is the intention of the Commission that the AI Act will have this effect:

> *"To achieve those objectives, this proposal presents a balanced and proportionate horizontal regulatory approach to AI that is limited to the minimum necessary requirements to address the risks and problems linked to AI, without unduly constraining or hindering technological development or otherwise disproportionately increasing the cost of placing AI solutions on the market."*[12]

[8] See article 24 of the Draft AI Act: "Where a high-risk AI-system related to products to which the legal acts listed in Annex II, section A of the Draft AI Act, 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."

[9] More precisely the Medical Devices Directive (Directive 93/42/EEC), the Active Implantable Medical Device Directive (Directive 90/385/EEC) and the In-vitro diagnostics directive (Directive 98/79/EC).

[10] Blue Guide 2016, p. 11

[11] See article 1 (11) and (12) MDR and articles 1 (5) and (6) IVDR in relation to the EMC and Machinery Directives

[12] Explanatory Memorandum AI Act, p. 3

However, as will be discussed below, the AI Act fails to achieve this tested principle of NLF logic by providing for overlapping requirements that must always be applied, regardless of whether these are more specific than provided under the MDR and the IVDR. This creates incoherence and inconsistencies as demonstrated in section 3 of this legal analysis, because - as will be demonstrated in this section 2 of this analysis - there is not a regulatory *lacuna* regarding AI Act systems under the MDR and IVDR in the first place. Where the AI Act supplements the MDR and IVDR by addressing risks not addressed in the MDR or IVDR, we will demonstrate that more proportionate solutions are possible and are already used under the MDR and IVDR (in line with the so-called Machinery Directive model and the EMC directive model).

2.3 Regulation of AI systems under the MDR and IVDR

2.3.1 Scope

It is important to keep in mind that the MDR and IVDR are agnostic to AI systems as a technology and rather apply to electronic programmable systems in the broad sense.[13] For the purpose of the MDR and IVDR, "*AI is merely a way to implement digital systems*".[14] Unlike traditional engineering however, the final 'design' of an AI system might consist of a network layout accompanied by tens to hundreds of millions of floating point numbers, rather than documented, human readable software.[15] Digital systems that qualify as a medical device have been regulated under the predecessors of the MDR and the IVDR, the AIMDD, MDD and IVDD, for decades. The scopes of the MDR and IVDR concern all AI-systems in scope of the AI Act that also qualify as a medical device and many AI systems have been CE marked under the old medical devices directives.

An AI system is regulated under the MDR or IVDR if it qualifies as a medical device in the meaning of article 2 (1) MDR, an accessory to a medical device [16]or a product listed in Annex XVI of the MDR.[17]

If the device qualifies as a medical device, it can qualify as an in vitro diagnostic medical device (IVD) in the meaning of article 2(1) IVDR, in which case that device and its accessories[18] are regulated under the IVDR.[19] Both the MDR and the IVDR explicitly mention software in the definition of medical device[20] and IVD[21], bringing an AI system comprising software in scope of these two regulations. In the cases that an AI system is embedded in a hardware device, the device as such will fall in scope of the regulations if it meets the definitions of medical device or IVD.

An AI system as such comprises software and therefore could be placed on the market as:

- a medical device or in vitro diagnostic (IVD) medical device (the focus of this legal analysis)
- an accessory for a medical device or for an IVD medical device (accessories by definition do not fulfil a medical purpose on their own)
- a part or a component of a medical device, IVD medical device or Annex XVI device.

An AI system may also not be in scope of the definition of medical device because it does not have a medical intended purpose, but may nevertheless be regulated partly under the MDR as the AI-system forms part of a system in the meaning of article 22 MDR. A system concerns "*a combination of*

[13] See Annex I, section 17 MDR, and Annex I, section 16 IVDR
[14] H. Thimbleby, 'Digital maturity in an age of digital excitement Digital maturity goes beyond excitement to quality', BSI White Paper, p. 7
[15] A.A. Bharath, "Recent advancements in AI – implications for medical device technology and certification", BSI White Paper, p. 3
[16] Article 2 (2) MDR
[17] Article 1 (4) MDR
[18] Article 2 (2) IVDR
[19] Article 1 (2) IVDR
[20] Article 2 (1) MDR
[21] Article 2 (1) IVDR

products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose".[22]

The concept of '*medical purpose'* of software was already addressed in the MEDDEV 2.1/6-guidance, which has since been replaced by MDCG 2019-11-guidance under the MDR and IVDR 'Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR'. MDCG-guidance concerns guidance from the so-called Medical Device Coordination Group ("MDCG"), an expert group that advises the European Commission and assists the European Commission in ensuring the harmonized implementation of both the MDR and the IVDR. To achieve this purpose, the MDCG regularly publishes guidance on varying subjects under the IVDR and MDR. While the aforementioned guidance document does not refer to artificial intelligence as a technique, it does refer to many intended purposes of software that could be implemented by means of AI systems using techniques in Annex I of the AI Act, such as:

- Medical devices software ("MDSW") that uses maternal parameters such as age, concentration of serum markers and information obtained through foetal ultrasound examination for evaluating the risk of trisomy 21;
- MDSW that receives measurements from transrectal ultrasound findings, age, and in vitro diagnostic instruments and calculates a patient's risk of developing prostate cancer;
- Mass Spectrometry MDSW intended to analyse LC-MS/MS data to be used for microorganism identification and detection of antibiotic resistance; and
- MDSW smartwatch app, which is intended to send alarm notifications to the user and/or health practitioner when it recognises irregular heartbeats for the purpose of detecting cardiac arrhythmia.[23]

For software to fall within the scope of the MDR or IVDR, the software must either perform an action on data or perform an action beyond storage, archival, communication, simple search or lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data).[24] In addition, the action performed must be for the benefit of one or more individual patients.[25] Software that fulfils no medical purpose but that is intended to drive or influence the use of a medical device is also a regulated device under the MDR/IVDR.[26] If the software is solely intended to drive or influence the use of a hardware medical device, without by itself creating information for a medical purpose, then it is not considered medical device software, but nevertheless is covered by the regulation as an accessory for a medical device or IVD medical device or as an integral part or component of a medical device or IVD medical device.[27]

Article 5 of both MDR and IVDR provides that a device may only be placed on the market or put into service in the Union if the device complies with the MDR or IVDR. This means that the device has undergone conformity assessment in accordance with either the MDR or IVDR[28] after classification to determine appropriate conformity assessment route(s)[29], or is subject to an exemption to this. This means that the device has undergone conformity assessment in accordance with either the MDR or IVDR after classification to determine appropriate conformity assessment route(s), or is subject to an exemption to this. Such exception applies if the device qualifies as an in-house produced device used

[22] Article 2(11) MDR
[23] MDCG 2019-11, p. 7
[24] MDCG 2019-11, p. 8
[25] MDGC 2019-11, p. 8
[26] MDCG 2019-11, p. 8-9
[27] MDCG 2019-11, p. 17; BSI White paper" Software as a medical device A comparison of the EU's approach with the US's approach", p. 8
[28] See section 3.7.3. below
[29] See below in section 2.3.2

only in a health institution in the Union[30], a custom made device or a device for clinical investigation under the MDR[31] or performance studies under the IVDR.[32] Article 6 of both MDR and IVDR provides that AI systems qualifying as devices that are provided as a service at a distance into the Union and may not be placed on the market as a result still need to meet the requirements for devices under the MDR and IVDR.

MDCG 2019-11 provides examples of qualification of software as devices that may include AI systems in basically all cases, since most devices discussed in this guidance will comprise application of the techniques set out in Annex I AI Act, such as:

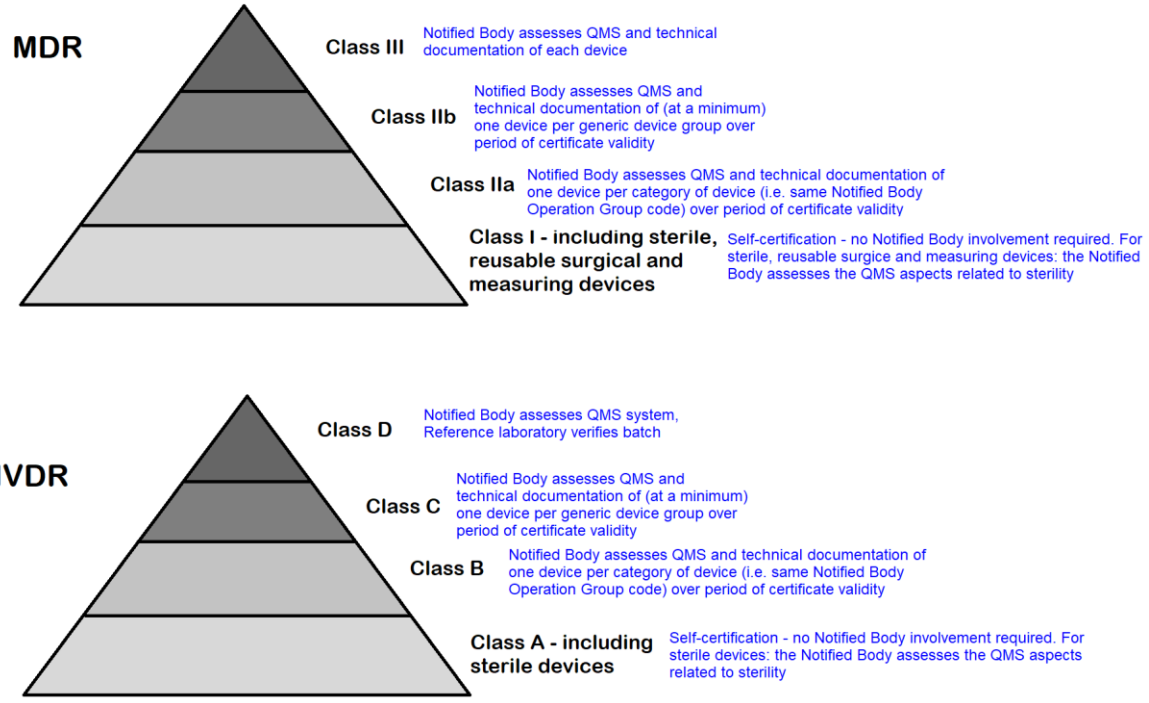
- Various decision support systems (radiotherapy treatment planning systems, drug planning systems (e.g. dose planning for chemotherapy) and Computer Aided Detection systems are intended to provide information that may suggest or exclude medical conditions (e.g analysis of x-ray images or interpret ECGs)[33];
- Software to monitor performance of medical devices[34]; and
- Expert systems used for capturing and analysing together one or multiple results obtained for one patient by means of in vitro examination of body samples (software integrating genotype of multiple genes to predict risk a disease or medical condition developing or recurring, software using algorithms for characterising viral resistances to various drugs, based on a nucleotide sequence generated by genotyping assays and microbiology software for the identification of clinical isolates and/or the detection of antimicrobial resistances)[35].

2.3.2 Classification

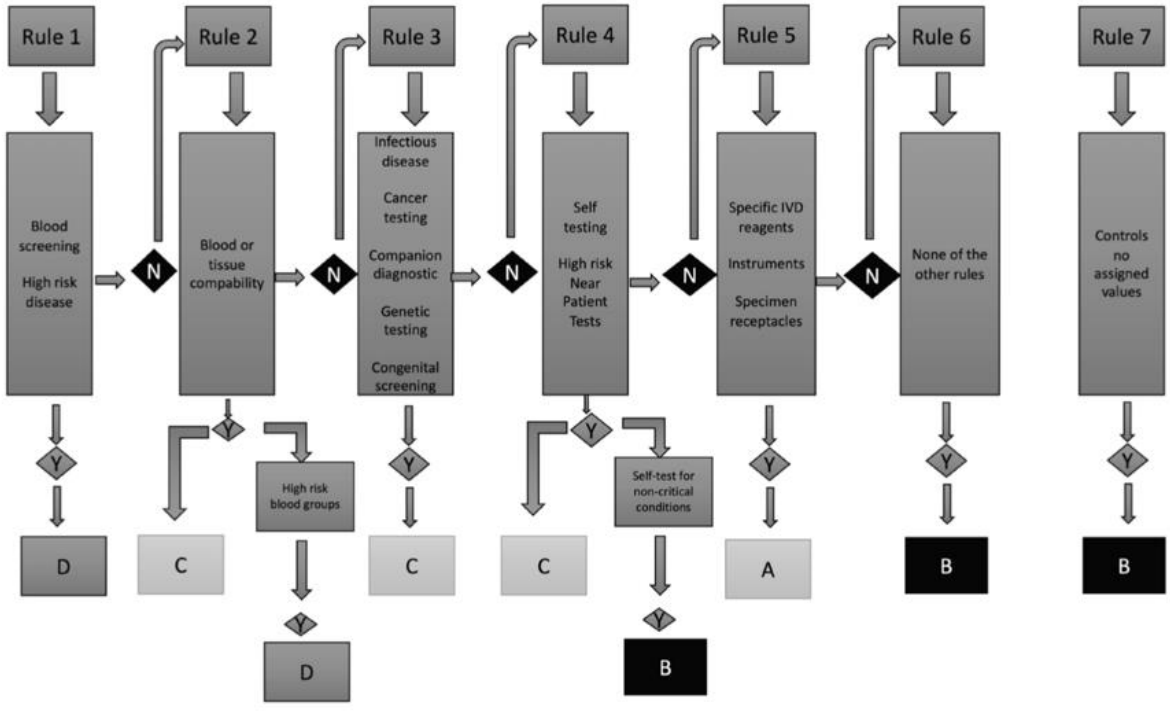
The conformity assessment routes available to the manufacturer of a software device depend on the classification of the device. Classification is carried out in accordance with Annex VIII MDR[36] or Annex VIII (for IVDs)[37]. The MDR distinguishes Class I, IIa, IIb and III, whereas the IVDR uses letters to distinguish the classes: Class A, B, C and D. The MDR also makes a distinction for Class I devices that contain a measuring function, are reusable surgical instruments or are sterile, while the IVDR makes a distinction for sterile devices.

From class IIa under the MDR (and for Class I sterile devices, measuring devices and reusable surgical instruments) / class B (and sterile devices) under the IVDR onward, involvement of a Notified Body is required in order to place the device on the market. The higher the risk class of the device, the more intense the scrutiny of the Notified Body, as is visualized hereinafter:

[30] Article 5 (5) MDR and IVDR
[31] Article 10(6) MDR
[32] Article 10(5) IVDR
[33] MDCG 2019-11, p. 19
[34] MDCG 2019-11, p, 21
[35] MDCG 2019-11, p. 22
[36] Article 51 MDR
[37] Article 47 IVDR



Classification according to IVDR is relatively straightforward, as the classification rules act as a waterfall mechanism guided by the intended purpose of the AI system/device – shown visually hereinafter:



An example of an IVD that comprises an integrated AI system would be a fully automated enzyme-linked immunosorbent assay (ELISA) analyser, composed of hardware and MDSW, intended to determine the Human Hemoglobine A1c ("Human HbA1c") concentration in serum in patients with Diabetes from the results obtained with a Human HbA1c ELISA.[38]

[38] MDCG 2019-11, p, 17

Classification of an AI system / device according to MDR, on the other hand, is more complex. Annex VIII of the MDR contains a specific rule for AI systems / devices as standalone software: rule 11, which applies to software intended to:

- provide information which is used to take decisions with diagnosis or therapeutic purposes; or
- monitor physiological processes,

both of which are typical for AI systems for medical or diagnostic purposes deployed in healthcare.

Rule 11 allows AI systems / devices comprising of only software to be classified anywhere from class IIa to III, depending on the risk. MDCG 2019-11 provides an illustrative table to determine the risk class by means of correlating the risk to patient to the significance of the information provided by the software in accordance with an IMDRF developed model[39]:

State of Healthcare situation or patient condition		Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
		High Treat or diagnose *~ IMDRF 5.1.1*	**Medium** Drives clinical management *~ IMDRF 5.1.2*	**Low** Informs clinical management *(everything else)*
	Critical situation or patient condition *~ IMDRF 5.2.1*	**Class III** *Category IV.i*	**Class IIb** *Category III.i*	**Class IIa** *Category II.i*
	Serious situation or patient condition *~ IMDRF 5.2.2*	**Class IIb** *Category III.ii*	**Class IIa** *Category II.ii*	**Class IIa** *Category I.ii*
	Non-serious situation or patient condition *(everything else)*	**Class IIa** *Category II.iii*	**Class IIa** *Category I.iii*	**Class IIa** *Category I.i*

Both the MDR and the IVDR explicitly state that, to the extent possible, guidance from the IMDRF must be taken into account in order to "*promote the global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations*".[40]

The application of the classification rules has been detailed for AI systems comprising medical device software in section 4 of MDCG 2019-11 and for AI systems not comprising software (e.g. because they are integrated in hardware) in MDCG 2021-24. Integrated AI systems may typically be covered under classification rules 9, 10, 11, 12, 13, 15 and 22 of the MDR.[41] For example, rule 22 on closed loop diagnostic systems that determine patient management by the device would apply to a defibrillator device with an AI system that determines if, when and what dose of electric shock to administer to the patient for treatment.

[39] MDCG 2019-11, p. 26
[40] Recital 5 to the MDR/IVDR
[41] MDCG 2019-11, p. 12

2.3.3 Modules

AI systems may consist of one or more software modules, some of which have an intended purpose that would qualify them as a medical device, whereas others may not. For example, an AI system for patient management may have a module for monitoring patients for a need to send medical alerts to the nurses' station and a module for modelling patient throughput in order to predict when a bed in a given department will be available for incoming patients.

Section 7 of MDCG 2019-11 provides guidance on how to segment larger systems in modules that do or do not qualify as medical devices, in order to permit a manufacturer to CE mark part of a system as medical device if this module can be distinguished clearly enough. This can lead to a situation where the draft AI Act is applicable to both the medical (partly) and non-medical (fully) modules of the system, provided that the whole system qualifies as AI system in the meaning of the draft AI Act.

3. Potential conflicts between AI Act and MDR/IVDR

3.1 Intro

The MDR and IVDR, and prior thereto the various directives, have been regulating the emerging AI systems in healthcare for years already and have accommodated inclusion of AI systems in the existing structure in an effective way. As stated above, for the purpose of the MDR and IVDR "*AI is merely a way to implement digital systems*".[42]

The overlay of the horizontal requirements brought about by the draft AI Act and the insufficiently precise connections between the draft AI Act on the one hand and the MDR/IVDR on the other hand (as evidenced by this legal analysis) have the potential to create a lot of additional work for manufacturers and health institutions to solve a problem that did not exist in the first place as there never was a regulatory vacuum for AI systems under the MDR and IVDR. Duplicative requirements will also put an additional strain on conformity assessment by notified bodies.

The classification rules for software devices and devices running software ensure that that all AI systems qualified as high risk under the draft AI Act and as devices under the MDR and IVDR are subject to notified body oversight by a notified body qualified to assess software.

As part of the drafting of this legal analysis, we have reviewed all 304 submissions to the Commission as part of the public consultation concerning the draft AI Act consultation as available on the website of the European Commission that have addressed the links between the MDR and the IVDR one way or the other.[43] These submissions are of varying degrees of detail and quality. We believe that especially the NEN Medical Device / AI Expert Group paper 'Feedback on the AI Act'[44] is of high quality in its impartial and technical analysis of the draft AI Act proposal for the interface with the MDR and the IVDR specifically. We have reviewed submissions in the consultation of the draft AI Act for feedback on the intersection of the draft AI Act with the MDR/IVDR specifically and found this to be the highest quality submission that did not come from a commercial stakeholder. Moreover, the paper addresses most of the points made in the submissions by commercial parties. While this legal analysis will have overlaps with that paper, we recommend using this paper to supplement this legal analysis and to consider requesting further advice from NEN on this subject during the legislative process.

The objective of the Commission is that "*as regards high risk AI systems which are safety components of products, this proposal will be integrated into the existing sectoral safety legislation to ensure consistency, avoid duplications and minimise additional burdens*".[45] In this chapter, we will analyze how well this objective has been met for the integration in the MDR and IVDR, which have been used to regulate devices that would qualify as high-risk AI systems under the draft AI Act.

[42] Professor Harold Thimbleby ,Digital maturity in an age of digital excitement Digital maturity goes beyond excitement to quality, BSI White Paper, p. 7

[43] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/feedbacken?pid=24212003

[44] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665329en

[45] Paragraph 1.2 of the explanatory memorandum to the draft AI Act.

3.2 Scope and definitions

3.2.1 Scope of definition of AI versus scope of definition medical device and IVD

The definition of an AI system in the AI Act is very broad:

> *"software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with"*[46]

The techniques set out in Annex I are:

> *"(a)Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;*
>
> *(b)Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;*
>
> *(c)Statistical approaches, Bayesian estimation, search and optimization methods."*

This definition will cover a large proportion of the software as medical device (SaMD) in scope of the MDR and IVDR as device. The MDCG's definition of scope of an SaMD in MDCG 2019-11 is such that the MDR and IVDR consider software a device if it is either:

- is comprised of a set of instructions that processes input data and creates output data[47] and is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the MDR or IVDR[48] (medical device/MDSW); or
- drives or influences the use of a device without having its own medical purpose or without creating its own information for medical purposes (accessory).[49]

The software in scope of MDCG 2019-11 will therefore always generate outputs such as content, predictions, recommendations, or decisions influencing the environments it interacts with. This patient specific output will basically always be generated by means of a rule, knowledge, or logic-based action different from storage, archival, communication or simple search.[50]

The techniques listed in Annex I of the draft AI Act are defined so broadly that they will capture basically any MDSW in scope of MDCG 2019-11. Especially the techniques named in sub b) and c) of annex I of the draft AI Act capture very basic software approaches for medical devices running software or comprised of software on the market today, such as simple rule-based decision tree models which are not generally associated with artificial intelligence. This makes the draft AI Act more a regulation of software related risk than a regulation of what is generally understood as artificial intelligence, such as deep learning. This overly wide scope exacerbates the consequences of inconsistencies, overlap and incoherence with the MDR and IVDR.

Examples of simple non-artificially intelligent medical software falling in the scope of the proposal range from medical device software embedded in electronic thermometers to alert the user when the temperature corresponds to fever, blood glucose meters and patient ventilators, migraine or asthma episode prediction apps, to medical image analysis software for tumour detection, as correctly identified by one of the parties participating in the public consultation for the draft AI Act.[51] Also, the definition of AI system would seem to cover all relatively simple chat bots or apps that do simple medical triage for lay users. As a result, the scope of the draft AI Act would cover software medical

[46] Article 3 (1) draft AI Act
[47] MDCG 2019-11, p. 5 (definition of software)
[48] MDCG 2019-11, p. 6 (definition of Medical Device Software)
[49] MDCG 2019-11, p. 5
[50] MDCG 2019-11, see step 3 in figure 1 on p. 9
[51] COCIR paper "COCIR Feedback Commission proposal for a European Artificial Intelligence Act", p. 2

devices and medical devices running software that are already very well understood and have been regulated without issues under the directives preceding the MDR and IVDR for a long time, as is witnessed by the 2012 MEDDEV 2.1/6 regarding qualification of software as medical device under these directives. This guidance document addresses software that performs actions on patient data for the benefit of patients going beyond simple search, communication, storage and lossless compression. The risks associated with this kind of software are well understood and are already addressed by the (current) legislative framework for medical devices.

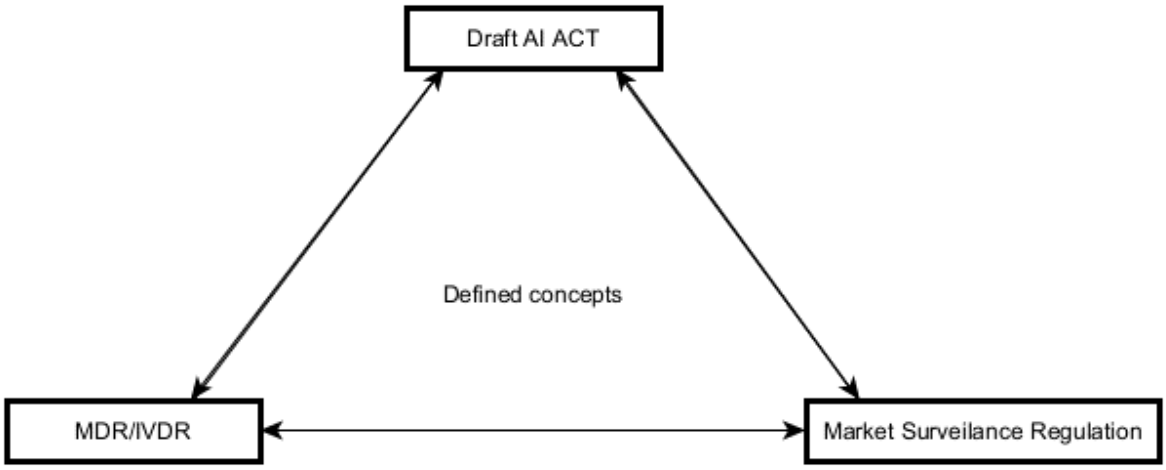
We understand that the overly wide scope of the techniques in Annex I has been recognized by the Council in its first partial compromise of 29 November 2021. In this compromise the Council has acknowledged that the definition of 'AI system' in the draft AI Act should be amended to exclude traditional software systems that are normally not considered as artificial intelligence.[52] However, such amended definition does not change the list of techniques included in Annex I of the same draft act, and therefore does not solve the problems related to scope raised in this advice.

3.2.2 Other definitions under the MDR/IVDR and draft AI Act, NLF and MSR

The MDR and the IVDR have been modelled on the New Legislative Framework ("NLF") and intends to align with this as much as possible.[53] While the draft AI Act states that it is based on the NLF as well[54], it modifies many of the concepts and definitions in ways that are contradictory and confusing while there is no formal hierarchy clause included in the draft AI Act (nor in the MDR/IVDR) to decide which of the overlapping regulations must be applied. As is explained below, this problem has been avoided for other horizontal legislation overlapping with the MDR and IVDR by including specific clauses in the MDR and IVDR that avoid overlap on procedural aspects and procedure related definitions.

This will not only affect manufacturers placing devices on the market having to comply with different but similar concepts under several regulations, but it will also lead to problems with market surveillance under the MDR, IVDR, draft AI Act and Market Surveillance Regulation (Regulation (EU) 2019/1020) ("MSR").[55] The Market Surveillance Regulation applies insofar a product regulation does not provide for more specific market surveillance rules.[56] This is made more complicated by the fact that an AI system can fall under both the MDR/IVDR and the draft AI Act, with the possibility of three sets of market surveillance rules applying to an AI system, using concepts with the same definition but different meanings:

[52] Council of Europe, Interinstitutional File 2021/106 (COD), dated 29-11-21 (14278/21), p. 3 (point 2(a))
[53] Recitals 25 and 26 MDR
[54] Recital 57 draft AI Act
[55] Recital 79 draft AI Act: MSR applies to draft AI Act too
[56] Article 2(1) Regulation (EU) 2019/1020



Examples of this include the concepts of 'importer', 'putting into service', 'provider' or 'user'. Below table shows definition inconsistencies between the MDR/IVDR, draft AI Act and the Market Surveillance Regulation and, where deemed relevant, comments on the consequences of the inconsistency. Where parties participating in the public consultation drew valid conclusions concerning the consequences of these inconsistencies, a reference to such consequences included.

Defined term	MDR/IVDR definition	Draft AI Act definition	Comment
User	*" 'user' means any healthcare professional or lay person who uses a device".* (article 2 (37) MDR) *" 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline".* (article 2 (38) MDR)	*" 'user' means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity". (*article 3 (4) draft AI Act) Recital 59): *"It is appropriate to envisage that the user of the AI system should be the natural or legal person, public authority, agency or other body under whose authority the AI system is operated except where the use is made in the course of a personal non-professional activity."*	Users for the purpose of the MDR/IVDR may use AI systems that are not 'under their authority' which would lead to different outcomes under the respective regulations. The concept of 'using' (MDR /IVDR) and 'operating under authority of' (draft AI Act) are different and can lead to different outcomes. The draft AI Act does not contain a concept of 'lay person user' which may be an important group of users under the draft AI Act for self-testing devices powered by AI. A lay person will usually not apply an AI system under his own authority. The question must also be raised how a lay user is supposed to fulfil the article 29 obligations (i.e. monitoring the operation of the AI system on the basis of the instructions for use and – where relevant – informing the distributor or provider)?
Putting into service	*" 'putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose".* (Article 2 (29) MDR)	*" 'putting into service' means the supply of an AI system for first use directly to the user or for own use on the Union market for its intended purpose".* (article 3 (11) draft AI Act)	The question must be raised whether the reference to "*own use*" is intended to create a different scope than is intended in the definition under the MDR.
Manufacturer / provider	*" 'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark."* (article 2 (30) MDR)	*" 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or*	'developing' is a concept that is not used in NLF logic (see also the MSR that does not recognize this concept). The question must be raised whether developing is also manufacturing or whether these terms have an entirely different meaning. Article 28 draft AI Act provides that importers and distributors become 'provider' if they place on the market or put into service under

		trademark, whether for payment or free of charge". (article 3 (2) draft AI Act)	their own name, which is in conflict with article 16 (1) (a) MDR and IVDR.
Importer	*" 'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market".* (article 2 (33) MDR)	*" 'importer' means any natural or legal person established in the Union that places on the market or puts into service an AI system that bears the name or trademark of a natural or legal person established outside the Union".* (article 3 (6) draft AI Act	Bearing trademark or name of person outside Union is anomalous (also with the MSR definition).
Distributor	*" 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service".* (article 2 (34) MDR)	*" 'distributor' means any natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market without affecting its properties". (article 3 (7) draft AI Act)*	The addition of the concept 'without affecting its properties' is not in accordance with the definitions in the MSR or in the MDR/IVDR. Also, the MDR and IVDR allow distributors to make certain changes to the device and its packaging / instructions for use. As correctly remarked during the public consultation, article 3 (7) of the draft AI Act, lacks the reference to the end point of responsibility of the distributor: *"up to the moment of placing on the market"*. Consequentially, the distributor obligations an AI system under MDR and draft AI Act can diverge without there being an adequate reason for such divergence. To repair this divergence, the specification *"up to the moment of placing on the market"* should be included in the definition of distributor under the draft AI Act.[57]
Serious incident	*" 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat*". (article 2 (65) MDR)	" 'serious incident' means any incident that directly or indirectly leads, might have led or might lead to any of the following: (a)the death of a person or serious damage to a person's health, to property or the environment, (b)a serious and irreversible disruption of the management and operation of critical infrastructure." (article 3 (44) draft AI Act)	Not only do the definitions of serious incident not match, unlike the MDR/IVDR the draft AI Act does not define the embedded term incident. Incident is defined in the MDR and IVDR as "*any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect*" (article 2 (64) MDR). Accordingly, it is not clear how a serious incident under the MDR and IVDR would relate to a serious incident under the draft AI Act.
Risk	" 'risk' means the combination of the probability of occurrence of harm and the severity of that harm". (article 2 (23) MDR)	Not defined, yet appears in the draft AI Act text 286 times.	As correctly addressed by commercial parties during the public consultation, the MDR and IVDR contain a risk-based classification system for medical devices, in relation to which risk is used as a core concept. Risk is also used as a core concept in the conformity assessment of devices. The draft AI Act does not define the concepts of risks or harm while using these terms generously throughout the draft act. As the AI Act and the MDR / IVDR cover similar matters in relation to AI qualifying as a medical device, such absence of a definition of risk is likely to cause unclarity and inconsistent interpretations. Industry predicts that this will result in

[57] BVMed paper, p.7

			"increased complexity and legal uncertainty concerning the overall compliance with relevant frameworks."[58]

In order to - at least - ensure consistency of application of rules and effective market surveillance, the NLF concepts in the draft AI Act should be defined identically as in the MSR (as has been ensured for the MDR and IVDR). This is especially important because the competent authority for market surveillance of the AI systems that are also devices in the meaning of the MDR or IVDR will be the competent authority for the MDR and the IVDR.[59] Market surveillance cannot be effective if the competent authority must apply multiple differently defined identical concepts simultaneously.

Terms such as 'provider', 'importer', 'serious incident', 'putting into service' and 'user' in the draft AI Act do not match those under the MDR/IVDR or under the MSR. This is problematic given the requirement under the draft AI Act to integrate the technical documentation required under the draft AI Act with the technical documentation required under the MDR/IVDR. This would result in one set of documentation using the same defined terms defined differently.[60] Especially problematic, as shown in the table above, is the definition of 'risk'. Risk is the main defined concept of conformity assessment under the MDR and IVDR but is not defined in the proposal for the AI Act. As a result, it is not clear whether the risks managed in the MDR / IVDR part of the technical documentation also manage the risks required to be managed by the draft AI Act or not.

Differing definitions between the draft AI Act and the MDR/IVDR will make the compilation of overlapping technical documentation as required under article 11 (2) draft AI Act[61] not only difficult but nearly unworkable in practice. This is caused by the impossibility to use one defined term for the same concept under the various regulations, because there will be different parts of technical documentation that use defined terms meaning different things.

3.3 Economic operator obligations

As will be set out in more detail below, the economic operator obligations for importers and distributors overlap but then diverge considerably in approach from the system under the MDR and IVDR. The MDR and IVDR impose a document and product-based check, while the draft AI Act requires more general compliance oversight of the manufacturer and importer (the latter in the case of the distributor). Without a hierarchy between the MDR/IVDR and the draft AI Act or a conflict provision that resolves this divergence, it means that the importers and distributors of AI systems that are also devices under the MDR / IVDR have significantly more far-reaching obligations under the draft AI Act than under the MDR / IVDR and must comply with a double set of rules for the same product.

3.3.1 Importer obligations

The verification obligations of importers under article 26 draft AI Act are not consistent with those for importers of devices under article 13 (2) MDR and IVDR. Only requirement 26 (c) under the draft AI Act ("*the system bears the required conformity marking and is accompanied by the required documentation and instructions of use*.") is similar to for device importers under article 13 (2) (a) and (d) MDR/IVDR. The other requirements under article 26 (a) and (b) of the draft AI Act comprise very qualified assessments that the importer will generally not be able to make and would not need to make

[58] Siemens paper, p. 3
[59] Article 63, 3rd paragraph, draft AI A
[60] See for more discussion section 3.5.3 on technical documentation
[61] See article 11 (2) draft AI Act: "Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts."

under the MDR and IVDR: has the right conformity assessment procedure been carried out (a) and is the technical documentation compliant with Annex IV? The importer will generally never have access to the technical documentation for a device. These requirements are more appropriate for the authorized representative, who has a specific role in checking compliance of the manufacturer under article 10 of the MDR and IVDR.[62]

3.3.2 Distributor obligations

The obligations of the economic operators under the draft AI Act do not dovetail with the MDR and IVDR well. The distributor shall verify under article 27 (1) draft AI Act that the high-risk AI system bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the system, as applicable, *have complied with the obligations set out in this Regulation*. This duty for the distributor to verify manufacturer compliance is very far going. The verification obligations of distributors for devices under article 14 (1) MDR and IVDR are limited to verification of documentary evidence that is available to them and which they can actually verify, such as a declaration of conformity. The distributor will generally have no means to verify compliance of the manufacturer.

3.4 Risk class of draft AI Act versus risk class of devices software

Devices must be classified under the MDR and IVDR intricate classification system in Annex VIII to determine the available conformity assessment routes. The draft AI Act also uses a classification system, but this classification system is simple and binary. The legislator has realized that the draft AI Act may impact on classification under the MDR and IVDR in recital 31 draft AI Act:

> *''The classification of an AI system as high-risk pursuant to this Regulation should not necessarily mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered 'high-risk' under the criteria established in the relevant Union harmonisation legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council and Regulation (EU) 2017/746 of the European Parliament and of the Council, where a third-party conformity assessment is provided for medium-risk and high-risk products."*

As explained in this legal analysis, all devices in the meaning of the MDR or IVDR (i.e. all healthcare related AI systems) automatically qualify as 'high risk' under the draft AI Act with no further risk stratification possible (contrary to the MDR and IVDR). At the same time, risks related to health of patients are already addressed in MDR and IVDR, as they have been for all AI systems already certified under the predecessors of the MDR and IVDR and the MDR itself. This leads - for example - to the confusing consequence that an AI system may be classified as 'high-risk' under the draft AI Act while being classified as 'medium risk' (class IIa or B, for example) under the MDR or IVDR. This is more pronounced even for low-risk legacy devices under the MDR. In addition to devices classified for the first time under the MDR or IVDR, there are also the devices that will still be on the market until 26 May 2024 as legacy device classified under the MDD on the basis of the transitional regime of the MDR. Essentially this means that many low-risk class I MDSW devices still on the market under article 120 (3) MDR until 26 May 2024. This is also true for the IVDR now that this has been amended with its own legacy periods reaching into 2027. These legacy devices will be deemed high risk AI systems under the draft AI Act if the transitional regime is not carefully calibrated as discussed above.

The 'high-risk' classification under the draft AI Act appears to have no consequences for the conformity assessment, other than that the requirements from Annex III of the draft AI Act must be met additional to the MDR or IVDR requirements for conformity assessments.[63] There is furthermore a risk that the

[62] See article 11 MDR and IVDR
[63] See section 3.5 of this advice

high-risk classification under the draft AI Act influences the risk classification under the MDR or IVDR by introducing outcome bias based on the high-risk classification under the draft AI Act, resulting in devices being classified in a higher risk class than necessary.

We advise not to work with double risk classification because it will confuse software developers as to what specific risks require mitigation under draft AI Act, since the MDR and IVDR are very specific in that regard and do not have one size fits all classification and conformity assessment. This would be fine for AI systems that are only covered under the draft AI Act (just like the Active Implantable Devices Directive (one of the MDR's predecessors) started out with only one risk class), but this is not appropriate for software that is covered under both the draft AI Act and the MDR or IVDR. For clarity's sake, AI systems should only be classified under one regulation. Given the fact that they will be primarily reviewed under the MDR or IVDR, it would be appropriate to only classify them under these regulations and not under the draft AI Act.

3.5 Requirements for high-risk AI systems

Title III, chapter 2 of the draft AI Act ('Requirements for AI systems') contains a number of requirements that are also partially or fully covered by the MDR/IVDR, such as the obligation to implement a risk management system[64] and compose technical documentation.[65] This leads to overlapping and inconsistent obligations without a clear rule to decide which set of rules has precedence. We have proposed ways to solve this inconsistency below in section 3.6.

In the following sections in this section 3.5 we will demonstrate where the requirements are inconsistent.

3.5.1 Risk management systems

Risk management and the improved risk management system requirements may be considered the core of the safety aspects MDR and IVDR. A device cannot be approved under these regulations if the device has not been subjected to rigorous risk management during the design phase and remains subject to risk management under the post market clinical follow up of the manufacturer. The MDR and IVDR risk management requirements have been calibrated to the use of the device for medical purposes. As discussed above in relation to definitions, the definition of 'risk' (the main defined concept of conformity assessment under the MDR and IVDR) is not defined in the draft AI Act proposal. As a result, it is not clear in the technical documentation whether the risks managed in the MDR / IVDR part of the technical documentation manage the risks required to be managed by the draft AI Act or not.

In addition to the requirements for the risk management system (as discussed in article 9 of the Draft AI Act), the draft AI Act implements human oversight as a risk management measure, which is discussed below in section 3.5.5.1.

The draft AI Act risk management standard is that the risk management measures implemented shall give due consideration to the effects and possible interactions resulting from the combined application b of the requirements set out in this Chapter3. This is however a lower standard than required under the MDR / IVDR for devices. NEN observes in its paper (as aforementioned) in this regard:

> *"The AI Act requires manufacturers to identify the most appropriate risk management measures, and to test the AI system against preliminary defined metrics and probabilistic thresholds. These testing frameworks are not defined in the MDR and subsequent standards (IEC 62304:2006, IEC 82304 1:2016, ISO 14917:2019). Under MDR risks are required to be*

[64] Article 10 (2) MDR, Article 10 (2) IVDR, article 9 draft AI Act
[65] Article 10(4) MDR/IVDR, article 11 draft AI Act

reduced as far as possible, this is more rigorous than 'most appropriate risk management methods' as defined in the AI Act. Software medical devices are tested throughout their lifecycle per the processes defined in IEC 62304:2006), including rigorous clinical validation per MDR requirements (not existing in the AI Act). Additional testing frameworks under the AI Act would not benefit the already existing testing framework for medical devices.

In addition, current BSI/AAMI 34971 (under development) will address risk management requirements for medical devices and will address specific requirements for risk management for AI based medical devices. Other standards under development for risk management include ISO/IEC 23894 (at SC 42), for AI systems, do not address medical devices, and excludes risk management processes for safety and security, and leans heavily on ISO 31000:2018 which does not align in terms of definitions of risk with ISO 14971:20 21 for medical devices."[66]

This means the MDR and IVDR address the risks related to medical AI systems already, and to a higher standard than the draft AI Act, making the risk management requirements in the draft AI Act not only duplicative, but also impractical (as is discussed below in relation to human oversight in section 3.5.5.1). For that reason, we advise to provide for a better demarcation between the risk management system requirements under the draft AI Act and the MDR/IVDR. The clearest solution for all involved (stakeholders, notified bodies and market surveillance authorities appears to be to provide that risk management under other applicable legislation that are subject to a higher standard than under the draft AI Act do not need to be managed under the draft AI Act.

3.5.2 Data and data governance

Article 10(3) of the proposed legislation requires high-risk AI systems datasets to be "*relevant, representative, free of errors, and complete*."[67] In practice, however, this is often not possible because the data sets in healthcare are usually not entirely accurate and are influenced by variations in routine care based on care provider specific, regional or disease specific variations, as well as impacted by the possibility to access data under the General Data Protection Regulation (Regulation (EU) 2016/679, "GDPR") and local healthcare law (specifically due to limitations caused by medical confidentiality).

Also, the concept of 'error' is not defined in the draft AI Act. This was also noted by parties participating in the public consultation for the draft AI Act:

"The AI Act also fails to reflect the reality of software development – where for testing and validation of algorithms data sets with errors are used precisely to assess an AI system's accuracy and performance – when placed to interact with real-world data that is often faulty and incomplete. Regarding the latter, the AI Act does not state what constitutes 'completeness' of a data set or when it becomes (sufficiently) relevant and representative."[68]

Without agreement on standards for clinical data sets used as examples for AI systems that are devices, a requirements of error-free data is practically impossible to implement.[69] For this reason, in the United States of America, the U.S. Food and Drug Administration ("FDR") has focused on assessment of the quality system under which the AI system is developed rather than on the AI system as such.[70]For this reason, in the United States of America, the U.S. Food and Drug Administration ("FDA") has focused

[66] NEN paper, p. 5
[67] Article 10 (3) draft AI Act
[68] Siemens paper, p. 4
[69] A.A. Bharath, "Recent advancements in AI – implications for medical device technology and certification", BSI White Paper, p. 10.
[70] BSI White Paper " Recent advancements in AI – implications for medical device technology and certification", Anil Anthony Bharath, Imperial College London, p. 11

on assessment of the quality system under which the AI system is developed rather than on the AI system as such.[71]

Therefore, the MDR and IVDR impose post-market clinical follow-up procedures, which have been adopted by manufacturers and approved by notified bodies to monitor data quality and outcomes for devices under the MDR and IVDR. Completely error-free data cannot always be ensured. Consequently, the current wording could prevent the use of data collected in a health care setting for training, validation and testing of the AI, thus potentially significantly hampering the availability of AI (due to difficulties in obtaining data for the initial training of the AI system) as well as post-market clinical follow-up ("PMCF") / post-market performance follow-up ("PMPF") ('real world') data collection, which is an obligation under the MDR and IVDR to monitor in the post-market phase how the devices is performing in the real world. Article 10 (3) of the draft AI Act should therefore be consistent with Recital 44 of the draft AI Act, which states:

"… Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the intended purpose of the system. They should also have the appropriate statistical properties, including as regards the persons or groups of persons on which the high-risk AI system is intended to be used. In particular, training, validation and testing data sets should take into account, to the extent required in the light of their intended purpose, the features, characteristics or elements that are particular to the specific geographical, behavioural or functional setting or context within which the AI system is intended to be used."[72]

This objective can be achieved by adding "sufficiently" rather than 'error-free and complete' to the requirements for training, validation and testing data as laid down in article 10 of the draft AI Act.

The draft AI Act requires discriminatory impacts to be set out in technical documentation (Annex IV.2 (g): "*the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system*"). However, with medical or diagnostic algorithms under the MDR and IVDR it is often not possible to determine during the phase of initial software validation or during clinical investigation if the algorithm will have any discriminatory impacts. Since furthermore no clear criterion or standard is provided for determining what is '*foreseeable*' the standard under the AI Act are unclear, causing a secondary unclarity about the risks to be managed under the AI Act. This makes in its turn the requirement in the technical documentation unclear. For a medical device under the MDR or IVD under the IVDR,such outcomes are addressed in the software risk management process which is subject to (harmonized) standards. Obviously, a discriminating algorithm will lead to different risks for the group of patients that are discriminated against, making this a health risk management issue under the MDR / IVDR in any event, rather than a more abstract discrimination issue under the AI Act, since the MDR and IVDR are only concerned with health related safety and performance – while the AI Act requirement is broader.

AI is often not built to discriminate but may develop discriminatory side effects as the AI develops after being put into service. This is precisely one of the things that a manufacturer of the medical device must track in the post market phase as part of the PMCF/PMPF process.Under article 64 and Annex VII of the draft AI Act economic operators are required to provide notified bodies and post-market surveillance authorities full access to training datasets. This may not be possible in a number of scenarios. For example, manufacturers may not have direct access to training data if the AI system has been developed using federated learning. There may also be copyright or privacy restrictions regarding training data sets. The latter is especially relevant in light of the informational obligations of a controller in relation to the personal data: sharing the data with third parties requires that the data subject is informed thereof. An additional legal basis may in addition also be necessary.

[71] BSI White Paper " Recent advancements in AI – implications for medical device technology and certification", Anil Anthony Bharath, Imperial College London, p. 11

[72] Recital 44 to the draft AI Act

3.5.3 Technical documentation

Article 11 (2) draft AI Act provides that:

> *"Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts."*

The requirement under article 11 (2) draft AI Act assumes that there will be no overlap in technical documentation between a device and an AI system, but as is demonstrated in this paper there is a lot of overlap and duplication.[73] For example:

- section 1 (general description) and section 2 (detailed description of elements of the AI system), are covered in Annex II, section 1 MDR / IVDR (device description including variants);
- section 2 (process for development of the AI system) is covered in Annex I.17 MDR and Annex I.16 IVDR for the General Safety and Performance Requirements ("GSPRs") against which IEC 62304 is harmonized; and
- section 4 (detailed description of the risk management system in accordance with Article 9 draft AI Act) is covered in Annex II, section 5 MDR / IVDR.

This means that in the end the manufacturer of the device is forced to do significant double work because he has to check if all technical documentation elements from Annex IV of the draft AI Act have been addressed in the Annexes II, III and XIV (MDR) or XIII (IVDR) technical documentation for the device. This could be remedied by rather specifying in the draft AI Act which elements of the technical documentation do not need to be provided in an overlap scenario as set out in Article 11 (2) draft AI Act. Team NB, the association of MDR and IVDR notified bodies, has warned against parallel document requirements, in the paper it filed during the public consultation.[74]

3.5.4 Transparency and Information to users

Article 13 of the draft AI Act contains a provision about provision of information to users, which is not nearly as detailed and specific as the provisions on provision of information to be provided with the device under Annex I.23 MDR and Annex I.20 IVDR.

Article 13 (1) AI Act provides a design requirement in that High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. This requirement is a mix of risk management by design and usability design. The MDR and IVDR mandate risk management and usability design, requiring the manufacturer to make the AI system transparent to the user or third parties insofar as is needed for safe use and required maintenance. Harmonised standards for software under the MDR and IVDR, such as the EN IEC 62304, EN ISO 62366 and EN ISO 14971 standards, oblige the manufacturer to use transparent design processes and the manage any risks related to the usability of the use interface and results provided in it. Since this requirement is already sufficiently addressed under the MDR and IVDR, It is superfluous for AI systems that are also devices in scope of the MDR and IVDR.

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[73] NEN finds that "The requirements regarding Technical Documentation in the current proposal of the AI Act are mostly already captured throughout the various requirements applicable to medical devices, such as the Annex II, III and XIV, and the various MDCG documents.", NEN paper, p. 6

[74] Team NB draft AIA position paper, p. 2

In addition, article 13 (2) draft AI Act provides that the instructions for use should be provided in "*in an appropriate digital format*" whereas the MDR and IVDR prohibit providing instructions for use in any other form that paper, except in the case of very specific medical devices under the MDR that are intended for professional use only.[75] The IVDR does not allow provision in digital form under any circumstance. This is a clear contradiction in regulatory requirements between the draft AI Act and the MDR/IVDR. However, as was observed by the submission of the Council of European Dentists (CED) in the public consultation, algorithmic transparency is crucial and must be achieved via clear standards and binding assessment criteria:

> *"Algorithmic transparency is also crucial to ensure patient rights to information and explanation of how a decision might have been reached. Clear standards and legally binding assessment criteria to ensure transparency of AI systems in healthcare are needed."*[76]

3.5.5 Human oversight and logging by user

3.5.5.1 Human oversight

While the MDR and IVDR incorporate usability explicitly in their risk management, the draft AI Act does not seem to do so as usability is not mentioned at all as concept in the draft AI Act. At the same time article 14 of the draft AI Act states that high-risk AI systems (i.e. AI systems qualifying as devices) should be designed and developed in such a way that natural persons can oversee their functioning. For this purpose, appropriate human oversight measures should be identified by the provider of the system to ensure that the system is responsive to the human operator. These are precisely the kind of requirements that are already addressed under the MDR and IVDR in detail, especially where it comes to active devices (e.g. software that can produce the wrong results or control of another device) and ((capital) equipment that can injure a user of patient when operated wrongly). The requirements set out in article 14 make it very unclear how to translate these requirements to risk management and usability design for a medical device in a way that is useful to the professional user. This was also observed by the submission of the Council of European Dentists (CED) in the public consultation:

> *"The draft Regulation would need to clarify how human oversight and the provision of information to users is defined and applicable, especially, examples from medical device software would be appreciated."*[77]

Implementing oversight for lay users will be even more challenging by the requirements of the draft AI Act, which lack any distinction between professional users and lay users like is made in the MDR and IVDR. An example of this is the imposition of additional usability requirements for self-tests, which contain transparency and oversight provisions already (did the test function correctly, and what does the user need to do in case of what test result?[78]).

High-level computing far exceeds human capabilities, which means that devices that have to rely on human oversight cannot carry out their functions as intended since their purpose is to provide solutions at a much higher speed and accuracy than humanly possible. Medical devices have been for example been developing into a more autonomous direction, with human oversight or other appropriate risk management measures dictated by the risk class of the device. For this reason, the MDR has a specific classification rule for closed loop systems[79]. Closed loop systems are placed in the

[75] Point 23.1(f), Annex I, of the MDR and Regulation (EU) No 2226/2021 ("e-IFU Regulation").
[76] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665510en
[77] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665510en
[78] Point 19 of chapter II, Annex I of the IVDR
[79] Rule 22, Annex VIII MDR: Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

highest risk class under the MDR because of their relative autonomy of functioning and are therefore evaluated most critically for appropriate risk management.

Tying the AI system's functionality to human oversight to the level of ensuring that the human operator can "*fully understand the capacities and limitations of the high-risk AI system*"[80] could be restrictive and would introduce new risks as functions might not be carried out quickly or sufficiently enough. This would render the development of certain medical devices (e.g. AI surgery robots) impossible, at a minimum for the European market as well as for providers established in the Union. More and more medical devices and IVDs are designed in a way that the human is kept out of the loop as much as possible nowadays, while the human operator is able to operate the device with risks managed for the intended purpose of the device without needing to have full understanding of capacities and limitations of the system. This is possible because the devices have been designed in a way that they are safe to use for the intended purpose, even if they are not fully transparent to the user.

Human oversight in itself is certainly warranted to reduce risks - nevertheless, it needs to be set at an appropriate level without inhibiting the initial function of the medical device AI system, as this could create new risks by itself and hamper innovation efforts.[81] The human oversight requirements in the draft AI Act are therefore too 'one-size fits all' to be useful, while the MDR and IVDR already contain a risk calibrated method for providing the appropriate solutions for managing the risk. The human oversight requirements in the draft AI Act are therefore too 'one-size fits all' while the MDR and IVDR already contain a risk calibrated method for providing the appropriate solutions for managing the risk. These risk may vary greatly on the risk profile of the device for patient and user and its degree of autonomy functioning. For example, the risk profile for patient and user will differ greatly between an autonomous AI powered surgical robot, an AI powered device for in situ testing for remaining cancer cells after excision of the tumor and an AI computer system that evaluates chest MRI scans for potential anomalies. These nuances are accounted for in the MDR's and IVDR's classification logic, but not in logic of the draft AI Act, which lumps all these devices in the same one size fits all high-risk bucket.

3.5.5.2 Logging

Transparency is certainly important for other purposes than human oversight during day-to-day use, such as preventative and corrective maintenance and actions, and analysis of the device's functioning for analysis of complaints and incidents. The logging capabilities prescribed in article 12 of the draft AI Act are intended to ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose of the system. They are particularly intended to enable the monitoring of the operation of the high-risk AI system with respect to the occurrence of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) of the draft AI Act or lead to a substantial modification and facilitate the post-market monitoring referred to in Article 61 of the draft AI Act. This shows that the logging capabilities are a function of risk management and software design requirements in this respect, both of which are accounted for under the MDR (GSPRs 17.1 and 17.2 and standards harmonized accordingly) and IVDR (GSPRs 16.1 and 16.2 and standards harmonized accordingly).

3.5.6 User obligations

Article 29 draft AI Act imposes a number of user obligations for users of high-risk AI systems that have no parallel in the MDR and IVDR, such as the obligation of a user to use the "*systems in accordance*

[80] Article 14 (4) draft AIA
[81] Spectaris paper, p. 4

with the instructions of use accompanying the systems". This obligation is not found in the MDR or IVDR any other NLF regulation or directive with regard to lay users or even professional users.

In addition, the requirement in article 29(3) draft AI Act that the "*user shall ensure that input data is relevant in view of the intended purpose of the high-risk AI system*" puts an obligation on users that is meaningless in relation to lay users and assumes a degree of professionality that most users will not have nor are required to have. Professional users in health institutions will normally not have any influence over the input data either, because their role will be to deploy the device in accordance with the instructions for use. Consequently, they have no control over whether the data measured from a patient is 'relevant' to the system. Rather, all they can do is use the device in accordance with the intended purpose as clarified in the IFU, which makes the input data automatically relevant to the system. For example, an AI system trained and intended to interpret MRI scans for signs of cancerous growths in lungs should evidently not be used to interpret MRI scans of other organs for the same purpose because those other MRI scans would not be relevant to the system in view of its intended purpose. However, this already covered under the MDR and IVDR under the obligation to not use the device off-label (i.e. not as intended). The manufacturer will have needed to engineer the system to reduce this risk, for example by having the system prompt the user that the 'other organ' scan presented is outside the scope of what the system is intended to interpret.

Ensuring that the input data is relevant for the device's operation will be subject to processes of risk management and usability design under the MDR and IVDR (as well as labeling), as to reduce the risk that the user makes a user error by providing the system with non-relevant data as in the above example with MRI scans. An obligation for the user to provide the system with relevant data is a reverse approach in the logic of the MDR and IVDR, which require that devices are designed in a way that they accept only relevant data as relevant. Users of devices in healthcare settings often do not exercise control over the input data nor do they have the means to evaluate if the input data is 100% relevant to the device, because the function of the device is to make sense of the data for them. This is especially relevant in cases where devices provide risk scoring based on a large number of data fields in the patient's health record. In a healthcare setting, devices should rather be designed in a way that they will not accept or alert the user to non-relevant or inappropriate data that is being fed into the system. An example of this is an AI system for interpreting lung images that is accidentally fed a kidney scan. In that case the MDR requires that the manufacturer tries to engineer the system in a way that it will question the input.

NEN observed in this respect in its paper for the public consultation:

> *"The requirements for users (article 29), introduces requirements which are not covered by MDR, and places additional burden on healthcare organisations, for example the collection of logs places an additional administrative burden for healthcare providers. Such logs and information are currently already required to be maintained by the provider under article 20 of the AIA, moreover, manufacturers are already obliged under the MDR to collect post market surveillance data re levant to the safety and performance of medical devices in the field."*[82]

Both the notified body (*ex ante*) and the competent authority (*ex post*) exercise oversight of proper implementation of risk management elements discussed above under the MDR and IVDR. The manufacturer must monitor, as a matter of post market surveillance, whether the risks discussed are indeed managed and users do not provide the system with non-relevant input.

3.5.7 Accuracy, robustness and cybersecurity

Article 15 (1) draft AI Act provides that:

[82] NEN paper, p. 3

> *"High-risk AI systems [i.e devices under MDR and IVDR] shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle."*

This requirement is duplicative of the requirements in GSPR 17.2 and 17.4 (Annex I MDR) and GSPR 16.2 and 16.4 (Annex I IVDR).

3.6 Concurrent regulation without conflict rules

As specified in the foregoing, devices will be concurrently regulated under the MDR/IVDR and draft AI Act. This means that article 10 MDR and IVDR, which contain the core obligations for the manufacturer of a device, apply concurrently with the obligations of the provider of an AI system under the draft AI Act. This would not be a problem if there was a clear hierarchy provision in the draft AI Act with respect to overlapping obligations and procedures, which is lacking. The problem of overlapping obligations and procedures is compounded by the fact that the draft AI Act uses defined terms that are not only inconsistent with the MDR/IVDR but also with the general NLF terminology as defined in the MSR, as was discussed above.

For this reason of possible overlap, the MDR and IVDR has been designed with overlap in mind with horizontal legislation. Several mechanisms are in place for overlap with various product regulation and horizontal legislation, such as the Machinery Directive, the Low Voltage Directive ("LVD") and the Electromagnetic Compatibility Directive ("EMC"), in which cases no additional CE marking under the Machinery or LVD/EMC directives is required, because their requirements are subsumed in the MDR/IVDR GSPRs.[83] In the case of the Machinery Directive additional elements of the essential safety and health requirements in Annex I of that Directive must be met if a relevant hazard under that Directive exists to which the requirements are more specific than those under the MDR/IVDR.[84]

The MDR and IVDR also have a system for application of directives or regulations with additional CE marking obligations additional to the MDR/IVDR, such as under the Restriction of Hazardous Substances Directive ("RoHS") and Radio Equipment Directive ("RED").[85] In those cases the declaration of conformity under the MDR/IVDR can declare conformity to all directives/regulations applicable to a single product.[86] The draft AI Act does not contain a similar option under article 19 draft AI Act, but rather provides in article 48 (3) that:

> *"Where high-risk AI systems are subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all Union legislations applicable to the high-risk AI system. The declaration shall contain all the information required for identification of the Union harmonisation legislation to which the declaration relates."*

Since conformity has to be declared with both the draft AI Act and the MDR/IVDR (and perhaps other legislation applicable, e.g., EMC, LVD, RoHS and RED) for a hardware device running an AI system or even for a pure software-based AI system, it is not clear which provisions of the inconsistent overlap between the MDR / IVDR and the draft AI Act are in fact declared conformity against. It would logically not be possible to declare conformity to both the draft AI Act and the MDR / IVDR where the

[83] Recital 16 MDR; recital 14 IVDR
[84] Article 1 (12) MDR; article 1 (6) IVDR
[85] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ L 174, 1.7.2011, p. 88–110 and Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, OJ L 153, 22.5.2014, p. 62–106
[86] Article 19(2) MDR / article 17(2) IVDR

obligations overlap but are inconsistent (as described in sections 3.5.1 t/m 3.5.7 of this legal analysis). It would logically not be possible to declare conformity to both the draft AI Act and the MDR / IVDR where the obligations overlap but are inconsistent (as described in the foregoing in sections 3.5.1 t/m 3.5.7 of this legal analysis). Therefore, the current solution adopted in the draft AI Act does not work in the situations where there is more specific NLF product regulation such as the MDR and IVDR.

In summary, NLF legislation with links to MDR and IVDR has adopted three different solutions for managing the overlap:

1. The Machinery Directive model: if the horizonal legislation contains more specific requirements to manage a specific hazard, the more specific essential requirements of the horizontal legislation apply (and must be addressed in technical documentation) but the CE mark is based only on the MDR or IVDR;
2. The EMC model: if the product specific regulation is capable of addressing the same hazards as the horizontal legislation, the hazards are addressed under the product specific regulation, which is referred to explicitly as a 'specific regulation' relative to the horizontal legislation; CE mark is based only on the MDR / IVDR.
3. RoHS/RED model: separate CE marking under both the horizontal and product specific regulation, but a single declaration of conformity and separate technical documentation.

In our view the best solution would be to make the MDR/IVDR a l*ex specialis* vis-à-vis horizontal legislation with overlapping obligations,[87] as has been provided for the in the MDR/IVDR already with regards to the EMC Directive[88] and the Machinery Directive.[89] In the case where the current AI acquis under the MDR/IVDR is deemed insufficient, there are effective and existing instruments for finetuning:

- In case of the option of the EMC model, the European Commission can facilitate harmonised standards under the MDR and IVDR to address the essential requirements of the draft AI Act under the broadly formulated GSPRs in section 17 and 16 of Annex I under the MDR and IVDR respectively;
- In case of the Machinery Directive model, essential requirements from the draft AI Act and corresponding harmonised standards are copied into the MDR/IVDR by reference; and
- Where there are remaining gaps, the Commission can decide to facilitate Common Specifications under article 9 MDR/IVDR for AI under the regulations or amend the GPRS under the MDR/IVDR by implementing act pursuant to article 5 (6) MDR.

There should at least be a solution in the draft AI Act to avoid, in addition to an overlapping conformity assessment under criteria from the draft AI Act and MDR/IVDR the application of parallel quality management systems[90],[91] and integrated technical document because in all of these cases the draft AI Act uses differently defined concepts[92]. This makes it impossible for manufacturers to have reliable quality system procedures (as they may differ between regulations) and consistent technical documentation (since this uses NLF terminology that is inconsistent between the AI Act and the MDR/IVDR).

[87] This was also proposed by NEN's AI group, see NEN WG response, p. 2
[88] Recital 16 MDR; recital IVDR
[89] Article 1 (12) MDR; article 1 (6) IVDR
[90] See this legal analysis, section 3.8.1

[91] See this legal analysis, section 3.8.4

[92] See this legal analysis, section 3.8.1 regarding QMS; see this paper, section 3.8.4 regarding incident reporting

In this sense it should be remarked that the Explanatory Memorandum of the AI Act intended that overlap between the AI Act and product specific legislation to be managed like is the case currently with the Machinery Directive, since high risk AI-systems are safety components of products regulated under product specific regulation:

> *"With regard to the interplay of requirements, while the safety risks specific to AI systems are meant to be covered by the requirements of this proposal, NLF legislation aims at ensuring the overall safety of the final product and therefore may contain specific requirements regarding the safe integration of an AI system into the final product."*[93]

Our conclusion is that either the Machinery Directive model or the EMC model should be implemented for the AI Act as both of these solutions safeguard consistency of NLF legislative terms (thus avoiding a rewrite of the NLF part of the AI Act) by keeping conformity assessments and related documentation separate. These are also accepted and proven solutions for managing overlaps between horizontal and product specific NLF legislation. Finally, adopting either of these models keeps the conformity assessment under the MDR / IVDR, avoiding the need to notify additional notified bodies for the AI Act for the nexus with medical devices / IVDs. Finally, it alleviates the pressure on competent authorities and notified bodies to hire additional AI experts for the medical field, because MDR and IVDR can continue to be administered as they currently are.

3.7 Kits and systems

Article 24 draft AI Act provides a kind of kit/systems provision for devices regulated under the MDR / IVDR and qualifying as high-risk AI systems under the draft AI Act (which will be the case for basically all devices, see section 3.5) combined with AI systems under which:

> *"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 provision is exactly duplicative of article 22 MDR and therefore a source of confusion, because article 22 MDR ensures compatibility between the devices and other products in the system, whereas article 24 draft AI Act does not require this. The IVDR does not have a similar systems provision, but works with the concept of kit as a singular device.[94] Article 24 is however contrary to the principle laid down in NLF regulation that requirements under the horizontal legislation (draft AI Act in this case) only need to be met in case they are more specific than the requirements under the product specific regulation (MDR or IVDR in this case).[95] There seems to be an NLF-unlike assumption underlying the draft AI Act that there is no product specific regulation that may already cover AI systems and that imposing draft AI Act requirements may lead to duplication.

3.8 Quality system procedures

3.8.1 Draft AI Act QMS

The draft AI Act requires implementation of a quality management system to ensure compliance with the draft AI Act in article 17 draft AI Act, just like the MDR and IVDR require implementation of a QMS in article 10 (9) MDR and IVDR. Many of the QMS elements mentioned under article 17 draft AI Act are duplicative with the MDR and IVDR or are similar but not the same, leading to confusion

[93] Explanatory Memorandum, p. 4
[94] See defined term kit in article 2(11) IVDR and kit in the definition of in vitro diagnostic medical device in article 2(2) IVDR.
[95] See above in section 2.2

about whether the draft AI Act requires additional work or not, as discussed in detail in the below table[96]:

Requirement draft AI Act	Requirement MDR/IVDR	Duplicative / similar / different	Comments
Strategy for regulatory compliance (article 17 (1) (a))	Strategy for regulatory compliance (article 10 (9) (a) MDR / IVDR)	Duplicative	-
Design control, verification and design (article 17 (1) (b))	Product realization, including planning, design, development, production and service provision (article 10 (9) (g) MDR / IVDR).	Similar	-
Techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system; (article 17 (1) €)	Identification of applicable general safety and performance requirements and exploration of options to address those requirements (article 10 (9) (b) MDR/IVDR)	Similar	-
Examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out (article 17 (1) (d))	Clinical evaluation (article 10(3) and 10 (1) (f) MDR) and performance evaluation (article 10(3) and 10 (1) (f) IVDR) Post-market surveillance (article 10 (1) (i), article 10 (10) MDR and article 10 (1) (i), article 10 (9) IVDR)	Similar	-
Technical specifications, including standards, to be applied and, where the relevant armonizedsed standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements (article 17 (1) (e))	Technical documentation must be in place in accordance with the requirements from the MDR/IVDR (article 10(4) MDR / IVDR). Devices that are in conformity with harmonized standards which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof (article 8 MDR/IVDR)	Different	
Systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems (article 17 (1) (f))		Different	Data collection/analysis/storage is not as such included as a separate requirement of the QMS. However, those subjects are also relevant to address under the MDR as part of the QMS e.g. with regard to the overall strategy for regulatory compliance and post market surveillance.
Risk management system (article 18 (1) (g), article 9)	System for risk management (article 10 (2) MDR/IVDR)	Duplicative	See also section 3.5.1 of this advice regarding the duplicative nature of the risk management system requirements in the draft AI Act

[96] See also a similar detailed comparison table in the NEN paper that uses a slightly different approach on p. 10

Post-marketing monitoring system (article 17 (1) (h))	Post-market surveillance system (article 10 (10) MDR, article 10 (9) IVDR)	Similar /duplicative	-
Procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62 (article 17 (1) (i)	Process for reporting of serious incidents and safety corrective actions in the context of vigilance (article 10 (9) (l) MDR / IVDR)	Duplicative	See also section 3.5.13.8.4 of this advice regarding the duplicative nature of vigilance reporting obligations in the draft AI Act
Resource management (article 17 (1) (l))	Resource management (article 10 (9) (d) MDR / IVDR)	Similar	-
An accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph (article 17 (1) (m))	Responsibility of the management (article 10 (9) (c) MDR/IVDR)	Similar	-
Implementation based on the size of the provider's organization (Article 17 (2))	n/a	Different	Implementation of QMS, based on the size of the provider's organization is not seen under MDR or IVDR
Article 17 (3)	n/a	Irrelevant	-

Where the QMS requirements are duplicative, they have (or can be) covered under the MDR/IVDR. Where the QMS requirements are similar or additional the gap to MDR/IVDR should be clarified.

Moreover, it is not clear how the essential world-wide standard for medical devices QMS ISO 13485:2016 will relate to the draft AI Act. This standard has a large (but not complete) overlap with the QMS requirements under the MDR and IVDR.

Article 17 (3) draft AI Act provides that providers of draft AI Act systems that are credit institutions regulated by Directive 2013/36/ EU, the obligation to put a quality management system in place shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive. It is therefore clear that deviations from the AI Act are possible in case of compliance with other harmonized legislation. In order to avoid the problems signaled above regarding overlap and inconsistency between the draft AI Act and MDR/IVDR it is recommended to include a similar provision exempting a manufacturer with a compliant MDR/IVDR QMS for draft AI Act QMS requirements in article 17 draft AI Act.

3.8.2 Change control

The MDR and IVDR work with three types of changes that have relevance in relation to the draft AI Act:

- Substantial modifications to a clinical investigation or performance study, which may include modifications to the study device[97];
- changes to the device, intended purpose or quality system that do not need to be reported to the notified body;
- substantial changes – changes to the device, intended purpose or quality system that must be reported to the notified body[98];

[97] Article 75 MDR / article 71 IVDR
[98] See Annex IX, 2.4 MDR and IVDR

- significant changes – changes to the device design or intended purpose of legacy devices that cannot be made after 26 May 2021 (MDR) or 26 May 2022 (IVDR)[99]

The question of what constitutes 'changes' in AI systems and the requirements for new submissions or notified body review in case substantial changes are made is an area of considerable unclarity and urgently needs additional clarification in order to not hinder innovative AI medical technologies to enter the market.

Recital 66 draft AI Act discusses the concept of substantial change in the draft AI Act as follows:

> *"In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, it is appropriate that an AI system undergoes a new conformity assessment whenever a change occurs which may affect the compliance of the system with this Regulation or when the intended purpose of the system changes. In addition, as regards AI systems which continue to 'learn' after being placed on the market or put into service (i.e. they automatically adapt how functions are carried out), it is necessary to provide rules establishing that changes to the algorithm and its performance that have been pre-determined by the provider and assessed at the moment of the conformity assessment should not constitute a substantial modification."*

A substantial change in recital 66 is defined in 3 (23) draft AI Act as "*a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed*". In addition, any significant change in design or intended purpose of an AI system placed on the market brings it in scope of the draft AI Act.[100] Here, the draft AI Act uses the concept of significant change, which – confusingly – is not defined in the draft AI Act. Accordingly, the draft AI Act uses the concepts of significant change, substantial change and substantial modification in unclear relation to each other, suggesting that these are one and the same concept yet not using consistently defined terms. This creates issues with application of the MDR and IVDR, because all three of these concepts have different functions under the MDR and IVDR, as described above, for the following reasons.

First, the concept of substantial modification is alien to MDR and IVDR for devices in the post-market stage because they work with the concepts of significant change and substantial change. The assumption that substantial modification would need to be notified under the draft AI Act would lead to the incoherent situation that an AI system could only be subjected to clinical investigation or performance study (i.e. experimental use on humans) when it has already been CE marked under the draft AI Act.

Secondly, the definition of 'substantial modification' in the draft AI Act assumes that every modification of the intended purpose of the AI system is under any circumstance a substantial modification, while under the MDR and IVDR not every modification of the intended purpose is a substantial modification that needs to be reviewed by the notified body.

Conversely, a pre-determined change (defined concept) in the meaning of the draft AI Act is not a substantial modification in the meaning of the draft AI Act (as follows explicitly from article 43 (4) draft AI Act) but may still be a substantial change in the meaning of the MDR or IVDR, because the MDR and IVDR do not work with the concept of pre-determined substantial changes.

NEN has observed in its paper about the draft AI Act that this leads to a very low reporting trigger:

> *"The AI Act implements a very low bar for reporting changes (Annex VII, 3.4) to the Notified Body. For example, it mentions that 'any intended change to the approved quality*

[99] Article 120 (3) MDR / article 110 (3) IVDR
[100] Article 83 (2) draft AI Act

management system or the list of AI systems covered by the latter shall be brought to the attention of the Notified Body by the provider'

Which will result in a heavy burden (human resources and costs) on manufacturers of medical devices and Notified Bodies as the current bar introduced in the MDR, is based on risk management, where reportable QMS changes shall only include substantial changes. Similarly, there is no room for sampling technical documentation in the conformity assessment procedure of the AI Act and the bar for reportable product changes is set at changes that may affect requirements of the system (Annex VII, 4.7), which would typically not be reportable under the MDR."[101]

This low reporting trigger results in inefficiencies and incoherence when implementing changes in AI systems that are also devices, according to NEN:

"[…] when introducing changes to the AI system (per 4.7 of Annex VII) if they potentially affect compliance against the AI Act need to be reported. Similarly, all changes to the quality management system (per 3.4 of Annex VII) need to be reported to the Notified Body. These processes place additional burden on an already heavily burdened and short staffed industry, thereby increasing the need for human resources, expertise and consequently costs. Additionally, the medical device industry is constantly working with clinicians in the field to guarantee quality, safety and fairness of medical devices."[102]

In addition to what NEN observes, this may concern changes that are not reportable under the MDR and IVDR, and only under the draft AI Act, meaning that a manufacturer of an AI system that is also a device needs to implement a two-step process to determine whether a change must be reported that addresses first reportability of changes under the draft AI Act and secondly reportability of changes under the MDR or IVDR. This is leads to an overly complicated burden for manufacturers.

3.8.3 Conformity assessment

Both the draft AI Act[103] and the MDR[104]/IVDR[105] require a conformity assessment. The MDR/IVDR only requires Notified Body involvement for devices classifying as Class I / A sterile (under the MDR also reusable surgical and measuring devices) / Class IIa / B and higher, whereas the draft AI Act requires Notified Body involvement for all AI systems that are devices. In both cases, the Notified Body will require review of the QMS and Technical Documentation.

This means in practice, that a manufacturer needs to select one Notified Body for the certification of the medical device components, and one for the certification of the AI components. Ideally, this would be the same Notified Body, which may be an MDR or IVDR accredited notified body, provided that this notified body has also been notified for the draft AI Act. Team NB, the association of MDR and IVDR notified bodies, has advised against splitting the draft AI Act and MDR/IVDR assessment over multiple notified bodies. This is to ensure that the special characteristic of medical devices and the general safety and performance requirements of a medical device are considered during the AI assessment, for which the non-MDR-accredited notified body does not have the respective expertise.[106]

Article 43 (3) draft AI Act seems to make provision for conformity assessment of AI systems by MDR / IVDR notified bodies:

[101] NEN paper, p. 7
[102] NEN paper, p. 7
[103] Article 43 draft AI Act
[104] Article 52 MDR
[105] Article 48 IVDR
[106] Team NB Position Paper draft AIA, p. 3

"For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply."

This looks more practical than it turns out to be on closer examination, because while the MDR and IVDR contain multiple conformity assessment routes associated with any of the four risk categories available under these regulations, the draft AI Act only has one conformity assessment route available for AI systems that are also a device under the MDR / IVDR. Accordingly, whilst the draft AI Act intends to combine the conformity assessment procedure of the MDR and draft AI Act, the draft AI Act requires each AI system (per Annex VII) to undergo the review by a Notified Body, where under the MDR, through various conformity assessment routes, technical documentation is sampled. In essence the draft AI Act imposes design dossier review for all high-risk AI, while design dossier review is mandatory under the:

- MDR only for a select group of high-risk devices (certain class IIb and class III devices);
- IVDR only for a select group of high-risk devices (certain class B, C and D devices).

This leads to incompatible assessment procedures for the same AI system/device, because a notified body cannot do a design dossier review for a product under one regulation (draft AI Act) and sample it under another (MDR/IVDR). As a result, all AI systems qualifying as devices would be subject to de facto design dossier review, which would be contrary to the conformity assessment system set up under the MDR and IVDR, as well as the classification logic for MDSW under rule 11 of Annex VIII MDR.

Moreover, as NEN observes in its paper,[107] within a single Notified Body, it may not be the same entity (or qualified person) responsible for the review. This will increase certification costs, audit and review time, burdening the already heavily burdened medical device Notified Bodies and manufacturers, and additionally Competent Authorities.

As a practical matter, it must be noted that both the draft AI Act[108] and the MDR/IVDR[109] require a written declaration that no application has been lodged with any other Notified Body for the same device/system. This requirement cannot be met if the same technical documentation is to be reviewed by independent Notified Bodies. This makes choosing notified bodies even more difficult, as under this limitation, a manufacturer of an AI system that is also a device under the MDR or IVDR can only use a notified body that has also been notified for the draft AI Act. This will apply even if the notified body was already accredited to do AI systems review under the MDR and/or IVDR. As a result, options for finding a notified body for conformity assessment are limited even more.

3.8.4 Vigilance and PMS reporting

3.8.4.1 Duplicative reporting systems

The MDR and the IVDR set up vigilance reporting systems with detailed reporting requirements in accordance with MDR- and IVDR-specific criteria that trigger the reporting obligation. The draft AI Act does not only use inconsistent and duplicative reporting criteria (see below in section 3.8.4.3 about Vigilance reporting) but sets up an entirely duplicative reporting structure[110] that will function in parallel to the EUDAMED database set up under the MDR and IVDR. Several stakeholders in the consultation have observed that the future European Database for Medical Devices (EUDAMED) should remain the system used for these purposes to ensure aligned, streamlined, efficient non-duplicative

[107] NEN paper, p. 6
[108] Annex VII of the draft AI Act
[109] Article 53(1) MDR, article 49(1) of the IVDR
[110] Article 62 re. draft AI Act reporting system

market surveillance of AI in/as medical technologies. Yet, the draft AI Act sets up its own reporting structure for post marketing monitoring (article 61) and incident reporting (article 62).

This will not only lead to double reporting obligations for stakeholders, but also to duplicative sources of reports, which will introduce inefficiencies in market surveillance over devices.

3.8.4.2 Post market monitoring / surveillance

The draft AI Act requires setting up a post-market monitoring system actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems (article 61 (1) and (2) draft AI Act). As discussed above in the light of comparative QMS requirements, this requirement is duplicative of the PMS and PMCF/PMPF requirements under the MDR/IVDR.[111] The post-marketing monitoring system (article 62 (3) draft AI Act) shows similarity with the MDR and IVDR post market surveillance system, except that the reporting obligations differ considerably as these are calibrated to the risk class of the device under the MDR and IVDR. Article 62 (4) draft AI Act provides that high-risk AI systems that are also devices do not need a fully duplicative post-marketing monitoring plan under the draft AI Act. However, the draft AI Act post-marketing plan requirements (among which monitoring of compliance with the requirements in Title III chapter 2 draft AI Act[112] that have been demonstrated in this advice to be largely inconsistent and/or duplicative with MDR/IVDR requirements[113]) must be integrated in the post market surveillance system and plan 'as appropriate'. Given the degree of inconsistency and overlap demonstrated in this advice, it seems very challenging and resource intensive for manufacturers of a device that is also a high-risk AI system to do this to the standard of 'as appropriate'.

Under the MDR/IVDR the manufacturer must actively involve other economic operators in the supply chain in post market surveillance (importer and distributors).[114] While the draft AI Act also imposes post marketing monitoring obligations, it does not require the provider to source post market information for economic operators or end users. Instead, it rather makes this an obligation of the provider only.

3.8.4.3 Vigilance reporting

As was shown above under the discussion of definitions in section 3.2, not only do the definitions of serious incident not match, unlike the MDR/IVDR the draft AI Act does not define the embedded term incident. Accordingly, it is not clear how a serious incident under the MDR and IVDR would relate to a serious incident under the draft AI Act. It is clear based on the comparison of the definitions in section 3.2 that the scope of the reporting obligations under the draft AI Act are much broader (since serious incidents under the draft AI Act encompass property damage for example, which are not in scope of the concept of serious incident under the MDR and IVDR).

As a result of the incongruence of the defined concepts of serious incident between the MDR/IVDR and the draft AI Act, a provider/manufacturer of an AI system that is also a device must undertake an unnecessarily complex analysis of any complaint or event and determine whether it is reportable under either the MDR/IVDR or the draft AI Act (e.g. in case of property damage), under both (in case of property damage and patient health deterioration) or under neither.

Then the right reporting forms must be used (one cannot assume that the draft AI Act forms are the same as the detailed, non-property damage oriented MDR and IVDR forms). The report must then be made to the competent authority for the MDR/IVDR, who will have to follow up on serious incidents

[111] See discussion of the draft AIA QMS in section 3.8.1 above
[112] See Article 61 (2) draft AIA
[113] See section 3.5 above
[114] Article 84 MDR/Article 79 IVDR and Annex III, 1.1. MDR and IVDR

that only qualify as such under the draft AI Act, unless these also qualify as serious incidents under the MDR/IVDR, while these are outside its normal healthcare scope of market surveillance. In case of overlapping application, the competent authority for medical devices and IVDs will suddenly see itself tasked with having to process serious incidents under the draft AI Act that would not be reportable under the MDR/IVDR. Examples would be cases where the event constitutes a non-reportable incident for the purpose of the MDR (e.g. a timely user discovered malfunction of the AI system without consequences for patients) but a reportable serious incident under the draft AI Act (e.g. the malfunctioning draft AI Act causes serious damage to property by destroying a multi-million piece of hardware). Under the AI Act the competent authority would be tasked for market surveillance tasks similar to those under the MDR and IVDR, which will require additional resources and scarce expertise.

The foregoing issue was also addressed during the public consultation on the AI Act. In its paper for the public consultation, Team NB has - for instance - strongly advised against multiple reporting channels and lines of communication to authorities and takes the view that the current, well established vigilance reporting mechanisms prescribed in the MDR and IVDR, which is now incorporated into the enacting provisions, should be used instead of developing a parallel approach.[115]

3.8.5 AI and clinical investigation under MDR / IVDR

Given the significant inconsistencies between MDR/IVDR and the draft AI Act regarding basic NLF definition it is not clear if a device that is provided for clinical investigation under the MDR or performance studies for the purposes must already be considered to have been placed on the market for the purposes of the draft AI Act. The draft AI Act does not make any explicit provision for clinical investigation or performance studies with medical devices or IVDs. Rather, the draft AI Act seems to assume that every AI system deployed must be 'finished', which is not the case for devices under clinical investigation or performance study. If this is indeed the assumption, an AI system subject to clinical evaluation or performance study will not be able to meet the requirements of the draft AI Act for finished draft AI Act systems, such as data quality (article 10 (3) draft AI Act) because the very nature of datasets used in clinical evaluation and performance studies is that the datasets themselves may not meet these requirements, if at all.[116]

Furthermore, a device under clinical investigation or performance study is not subject to the normal technical documentation requirements,[117] which means that the technical documentation integration mechanism foreseen in the draft AI Act[118] does not work for these devices.

The regulatory sandbox approach in article 53 draft AI Act does not seem to be an appropriate regulatory framework for testing and validation of AI system in clinical evaluation or performance studies.

Finally, the datasets resulting from clinical investigation and performance studies often comprised coded, locked datasets that are only fully transparent to the investigators of the trials in specified legal situations where a patient needs to be associated with an event. Yet, the draft AI Act requires (Article 64, Annex VII) that market surveillance authorities and notified bodies get full access to training, validation, and testing data sets. This requirement may be challenging or impossible to fulfil because providers/manufacturers may not be able to provide auditable access to training data if this data has been generated in clinical investigation or performance studies. In the context of federated learning (FL), developers have no direct access to data sets. They remain behind the security and privacy safeguards and are owned, for instance, by clinical investigators that may not be willing to grant access for ethical, regulatory, intellectual property or contractual reasons.

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[115] Team NB draft AIA position paper, p. 2

[116] As explained above, the requirements of data quality will be impossible to meet in healthcare, as has also been observed by a number of stakeholders in the draft AIA consultation.

[117] See Annex XV, chapter 2 MDR

[118] Described about in section 3.5.3

As was discussed in relation to change control in the foregoing 3.8.2, clinical investigation or performance study with medical devices or IVDs as affected by draft AI Act change management requirements. The concept of substantial modification is alien to MDR and IVDR for devices in the post-market stage, because both regulations work on the basis of the concepts of significant change and substantial change. The assumption that substantial modification would need to be notified under the draft AI Act would lead to the incoherent situation that an AI system could only be subjected to clinical investigation or performance study (i.e. experimental use on humans) when it has already been CE marked under the draft AI Act.

3.9 Notified bodies

At the moment, it is assumed that notified bodies that are currently already assessing AI systems under the MDR and IVDR will need to be re-assessed against the requirements in the draft AI Act. There is no mechanism for recognizing existing competence in the field of 'medical' AI under the MDR and IVDR while the draft AI Act requirements for designation of Notified Bodies, conduct of conformity assessments, and issuance of certificates differ in substance from the corresponding requirements of the MDR/IVDR. Notified bodies have just extensively been assessed under the MDR / IVDR. The number of Notified Bodies available to conduct conformity assessments according to the MDR and IVDR is already quite limited, leading to enormous bottlenecks in device manufacturers being able to commercialize products under these Regulations.[119] When the draft AI act is finalized, medical and in vitro diagnostic device Notified Bodies will also need to be designated under these new requirements. Additional accreditation of notified bodies against draft AI Act would however not bring more expertise, but just increase the administrative burden and by this reduce the already limited number of notified bodies and their capacity.[120] For that reason Team NB suggests in its admission during the public consultation using the existing authorization framework for notified bodies under the MDR and IVDR to expand the designation scope covering AI related aspects under relevant NLF regulations so that a notified body with a designation under MDR/IVDR would in this case need to show competency for assessing AI related aspects.[121]

Despite the identified need for notified body capacity to be progressively ramped up over time, this could again lead to bottlenecks and significant delays for medical and in vitro diagnostic devices that leverage AI. Experience with the MDR and IVDR has shown that it takes years for a notified body to be redesignated, even if the notified body already possesses the substantive expertise as will be the case with the notified bodies that are already assessing AI systems under the MDR and IVDR. As such, a pragmatic solution that enables Notified Bodies to be designated under the draft AI act in an expeditious manner and in alignment with MDR/IVDR requirements is needed. This solution could be a grandfathering mechanism under the draft AI Act for notified bodies already having AI systems in scope under the MDR and IVDR or it could be a sufficiently long transitional period for the draft AI Act for the redesignation process to complete. Experience with the MDR and IVDR has shown that this process can take two to three years easily. One of the bottlenecks in MDR and IVDR notified bodies redesignation is the lack of resources made available to the redesignation process by the Commission and the Member States. This is likely to be repeated under the draft AI Act as this process relies entirely on Member State resources.[122]

Delayed designations for the draft AI Act will lead to the situation that assessments for devices comprising AI systems cannot be completed by the notified body, delaying access to market of AI systems that otherwise would meet all requirements. If the notified body is not designated at all, the manufacturer will be forced to work with separate notified bodies, greatly complicating the conformity

[119] Refer to Joint Implementation Plan for MDR and IVDR
[120] Team NB position paper on draft AIA, p. 3
[121] Team NB draft AIA position paper, p. 3
[122] Articles 30-32 draft AIA

assessment process and increasing costs and resulting in delays of medical innovations reaching the market for the benefit of patients, as has become a grave concern under the MDR and IVDR.[123]

3.10 Transitional regime under MDR and IVDR and draft AI Act certification; draft AI Act transitional regime

The MDR and IVDR are currently, and will be for the coming years, still in transition to the new regime of conformity assessment and criteria under the new regulations. Article 120 MDR and article 110 (especially after adoption of the IVDR amendment currently in the final stages of the legislative procedure[124]) provide for an elaborate and complex transition regime that ends on 26 May 2024 for the MDR and 26 May 2027 for the IVDR. One of the core concepts of the transitional regime is the concept of 'significant change' as clarified in MDCG 2020-3 for the MDR. The concept of significant change in the meaning of article 110 (3) IVDR has not been clarified yet.

Article 83 (2) draft AI Act provides that the draft AI Act will apply to AI systems that are devices that have been placed on the market or put into service before the date of application of the draft AI Act referred to in Article 85(2), only if, from that date, those systems are subject to significant changes in their design or intended purpose.

There is currently no guidance available on what constitutes a significant change in design or intended purpose under the draft AI Act as this term has not been defined in the draft AI Act. Nor is clear how the interpretation of that term under the draft AI Act will be consistent with the similar terminology in the MDR and IVDR. If these are not interpreted exactly the same, a change that may trigger a significant change for the purposes of the draft AI Act but not for the MDR/IVDR, will trigger applicability of the Draft AI Act to the AI system in question and require conformity assessment by a notified body. Since many of these devices may be class I MDR or Annex III IVDR self-certified devices on the market under the article 120 (3) MDR or 110 (3) IVDR transitional regime, these devices would need to undergo conformity assessment by a notified body for the draft AI Act when this is not (yet) necessary under the MDR or IVDR.

In this light the transitional period of 24 months – as proposed in Article 85 - does not allow sufficient time for companies to adapt to such a complex and comprehensive regulatory framework as many stakeholders suggested but also not enough time to clear the 120 (3) MDR and 110 (3) IVDR transitional periods that may continue until 26 May 2027. The transitional periods for MDR and IVDR have been 4+3 years for medical devices until 206 May 2024 and 5+max 5 years for IVDs (if the IVDR amendment proposal is adopted). To make devices / AI systems subject to a double regulatory shift during this transitional period would be ill-advised.

3.11 In-house produced devices and AI certification

As has been described in relation of conformity assessment under article 43 (3) 1st paragraph of the draft AI Act, basically all devices comprising AI under the MDR and IVDR will need to be reviewed by a notified body, both for the MDR/IVDR assessment and for the draft AI Act assessment. There is however an important group of devices that are not subject to the normal conformity assessment procedures under the MDR and IVDR because they are not CE marked.

Article 5 (4) MDR and IVDR provides that devices that are manufactured and used within health institutions shall be considered as been put into service. The draft AI Act requires conformity

[123] See for example the press release of Kyriakides via https://medtech.pharmaintelligence.informa.com/MT144813/Find-Resources-To-Designate-IVDR-Notified-Bodies-Commission-Tells-Member-States

[124] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices, Brussels, 14.10.2021 COM(2021) 627 final

assessment under the draft AI Act for all AI systems put into service in the Union, which would apply to in-house manufactured devices under the MDR and IVDR as well. Article 5 (5) MDR and IVDR however provide that these devices are not subject to the normal conformity assessment procedures under these Regulations but are subject to self-assessment by the health institutions and subject to national competent authority ex-post oversight.

Thus, it is unclear under the draft AI Act what assessment procedure health institutions relying on article 5 (5) MDR or IVDR have to follow for the purposes of the draft AI Act. First, it is not clear if article 5 (5) MDR and IVDR qualify as a procedure 'enabling the manufacturer of the product to opt out from a third-party conformity assessment' in the meaning of article 43 (3), 3rd paragraph of the draft AI Act, which determines if the health institution must involve a notified body for draft AI Act requirements or not. Secondly, the requirements under the draft AI Act overlap partially with MDR and IVDR requirements, but also create additional and more specific requirements.

The draft AI Act makes provision for AI systems that are not subject to third party conformity assessment in Article 43 (3), 3rd paragraph:

> *"Where the legal acts listed in Annex II, section A, enable the manufacturer of the product to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may make use of that option only if he has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering the requirements set out in Chapter 2 of this Title."*

This provision might apply in case of in-house produced devices if it would connect to the MDR and IVDR logically and consistently, which it does not as it is not clear if the health institution qualifies as manufacturer as defined in the MDR and IVDR and because there is no 'opting' involved by the health institution. If article 43 (3), 3rd paragraph of the draft AI Act does not apply to in-house produced devices, the health institution must use the default conformity assessment route for high-risk AI systems, which requires involvement of a notified body for the assessment of the requirements in articles 8 to 15 of the draft AI Act (chapter 2 of title III draft AI Act) and the requirements under Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII draft AI Act by notified bodies which have been notified under the MDR and IVDR. The consequence is while the health institution is exempt from normal requirements of conformity assessment and notified body approval under the MDR or IVDR, it must nevertheless involve a notified body for the draft AI Act aspects mentioned in the previous sentence. As is explained in this legal analysis[125], the requirements in chapter 2 of title III of the draft AI Act overlap with the requirements in Annex I MDR and IVDR and add significant requirements.

The concept of regulatory sandbox introduced in the draft AI Act does not translate well to the in-house produced devices constellation under the MDR and IVDR, because the regulatory sandboxes concern development of AI before placing it on the market or putting it into service, while article 5 (4) MDR and IVDR provides that these devices are put into service.

Assuming that the health institution must involve a notified body for the assessment of the draft AI Act aspects of the in-house developed AI system, this would deprive article 5(5) MDR/IVDR of its useful effect because the intention of article 5(5) is to exempt in-house produced devices from normal conformity assessment procedures.[126]

Moreover, it would interfere with the national organization of healthcare that is Member States competence under article 168 (4) (c) TFEU within the scope of article 5 (5) MDR and IVDR as well as

[125] See section 3.5 of this legal analysis
[126] Recital 30 MDR, recital 29 IVDR

the subsidiarity choices made under the MDR and IVDR. The MDR and IVDR provides under article 5 (5) MDR and IVDR that oversight of in-house produced devices is Member State competence.

3.12 Market surveillance

Article 63 (3) draft AI Act provides that for the devices in scope of the MDR and IVDR the

> "*the market surveillance authority for the purposes of this Regulation shall be the authority responsible for market surveillance activities designated under those legal acts*".

This means that the medical devices NCA will need to be equipped with the necessary knowledge to be able to exercise effective market surveillance with regard to AI systems that are devices, because the scope of responsibility of the NCA becomes wider with the addition of the AI Act requirements in Title III chapters 2 and 3, which go beyond the scope of MDR and IVDR requirements.

The NCA will, furthermore, need to develop an enforcement policy for these additional requirements, which needs to be consistent with existing policy under the MDR/IVDR. This increased enforcement burden does not only apply to providers / manufacturers but also to the entire supply chain of AI systems (importers and distributors). Finally, while the MDR and IVDR do not impose direct obligations on users of devices (except to an extent for health institutions), the AI Act requires the NCA to also enforce against users of AI systems, for example as regards human oversight,[127] relevance of input data[128] and monitoring of the operation of the AI system against IFU provided specifications.[129]

Under the MDR and IVDR similar controls already exist, but these are subsumed into the manufacturer's pre-market obligation of risk management and usability design for the device, and in PMCF/PMPF obligations for the post-market phase. As discussed, the user obligations will generally be very hard to meet for users in a healthcare setting because of the complexity of input data and the limited control that the user has over the AI system, which is already designed to be as safe as needed under MDR / IVDR requirements.

Also, as discussed above in relation to vigilance in section 3.8.4, the competent authorities for medical devices / IVDs will be faced with the task of having to receive, process and administer vigilance reports under the draft AI Act for AI systems that are devices which do not constitute serious incidents for the purpose of the MDR and IVDR and therefore may not be health risk related but more general risk (but for example concern only property damage without any (in)direct risk to patients). Also, as discussed above in relation to vigilance in section 3.8.4, the competent authorities for medical devices / IVDs will be faced with the task of having to receive, process and administer vigilance reports under the draft AI Act for AI systems that are devices which do not constitute serious incidents for the purpose of the MDR and IVDR and therefore may not be health risk related but more general risk (but for example concern only property damage without any (in)direct risk to patients). This will add to their workload of processing of vigilance reports.

3.13 Further development of draft AI Act

The draft AI Act makes provision for further development by means of the law-making tool of common specifications, a tool shared with the MDR and IVDR. Where the draft AI Act provides for such options, it should be ensured that Common Specifications relevant to the field of healthcare are developed in cooperation with the MDCG, which plays a pivotal role in common specification under the MDR and

[127] Article 29 (2) AIA
[128] Article 29 (3) AIA
[129] Article 29 (4) AIA

IVDR.[130] More generally a connection between the European Artificial Intelligence Board under the draft AI Act and the MDCG is lacking in the draft AI Act.

At the very least the Commission should ensure that it or the European Artificial Intelligence Board consults the MDCG when it plans to propose Common Specifications under article 41 draft AI Act or when the Board develops common specifications[131] that may impact healthcare and remain consistent with similar concepts under the MDR/IVDR, such as common specifications regarding:

- the risk management system (article 9 draft AI Act, article 10 (2) MDR); and
- record keeping (article 12 draft AI Act, Annex I.17 MDR/Annex I.16 IVDR).

3.14 Other ways of including AI requirements under the MDR/IVDR

A number of stakeholders pointed out duplication between the draft AI Act and the MDR/IVDR and several solutions were proposed. In our view the most elegant solution would be to do an impact analysis of duplicative requirements between the draft AI Act and MDR/IVDR and identity the non-duplicative requirements. For example, submissions to the consultation have argued that articles 16-19, 21-23 and 25 draft AI Act are duplicative with the MDR/IVDR.[132] As we have demonstrated in this legal analysis, articles 9, 11-15 are (largely) duplicative as well.

The non-duplicative requirements can subsequently be implemented in the MDR / IVDR by means of amendment of the relevant GSPRs in Annex I by means of implementing act[133] or adoption of AI related standards to relevant GSPRs[134] This will allow for the harmonization of AI related standards under the MDR and IVDR or for the adoption of Common Specifications under article 9 MDR and IVDR. AI systems that are also devices can then be carved out from the draft AI Act. This solution was proposed for example by Roche in the public consultation for the draft AI Act.[135]

A large number of ISO/IEC standards relevant to AI systems in healthcare is currently under development and can be harmonized under the MDR and IVDR[136], and which address requirements under Title III chapter 2 draft AI Act, such as risk management and system bias:

- ISO/IEC 22989 Artificial Intelligence Concepts and Terminology
- ISO/IEC 23053 Framework for Artificial Intelligence Systems Using Machine Learning
- ISO/IEC 38507 Governance Implications of the Use of Artificial Intelligence by Organizations
- ISO/IEC 23894 Artificial Intelligence – Risk Management
- ISO/IEC TR 24028 Overview of Trustworthiness in Artificial Intelligence
- ISO/IEC TR 24368 Artificial Intelligence – Overview of Ethical and Societal Concerns
- ISO/IEC TR 24027 Bias in AI Systems and AI Aided Decision Making
- ISO/IEC TR 24030 Use Cases
- ISO/IEC TR 24029-1 Assessment of the Robustness of Neural Networks – Part 1: Overview
- ISO/IEC TR 24372 Overview of Computational Approaches for AI Systems

Many of these standards cover requirements in Title III, chapter 2 of the draft AI Act, demonstrating that these requirements are superfluous if imposed by horizonal legal instrument with the inconsistencies and incoherence demonstrated in this advice. Harmonised standards and Common

[130] See article 9 MDR and IVDR
[131] Article 58 (c) (ii) draft AI Act
[132] Medtronic paper
[133] Article 5 (1) MDR / IVDR
[134] E.g. GSPRs 1-8 which are concerned with risk management and GSPRs 17.1-4 (MDR)/16.1-4 (IVDR) which are concerned with software and programmable systems requirements
[135] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12527-Artificial-intelligence-ethical-and-legal-requirements/F2665165en
[136] BSI White Paper – Overview of standardization landscape in artificial intelligence, p. 4

Specifications have the enormous advantage that they are harmonised to the GSPRs of the given NLF rules, resulting in a clear overview of gaps not covered by the standard (the so-called Z-Annexes). This has been standard practice in medical devices for decades and has worked extremely well for all involved, from notified bodies to manufacturers and competent authorities.

In any event any harmonised standards adopted under article 40 draft AI Act should be relevant to healthcare

3.14.1 Conformity assessment

Conformity assessment is the process carried out by the manufacturer of demonstrating whether specified requirements relating to a product have been fulfilled.[137] The essential objective of a conformity assessment procedure is to demonstrate that products placed on the market conform to the requirements expressed in the provisions of the relevant legislation.[138] Under Union harmonisation legislation, conformity assessment procedures are composed of one or two conformity assessment modules. As products are subjected to conformity assessment both during the design and production phase, a conformity assessment procedure covers both design and production phases; while a module may cover:

- either one of these two phases (in this case a conformity assessment procedure is composed of two modules, e.g. Annex X coupled with XI MDR or IVDR),
- or both (in this case a conformity assessment procedure is composed of one module, e.g. Annex IX MDR or IVDR).

Conformity assessment of AI systems qualifying as devices follows the normal conformity assessment procedures under the MDR (article 52) and IVDR (article 48), which comprise a varying degree of review of the device design and the quality system depending on the assessment procedure chosen and the risk class of the device.

A crucial part of the conformity assessment for AI systems qualifying as devices is the assessment of compliance with the GSPRs in Annex I of the MDR and the IVDR. These GSPRs are a catalogue of requirements for all devices possible under the MDR and the IVDR, of which the manufacturer must determine if they apply to the device and if so, how the device meets the requirements.

For software the GSPRs on risk management (Annex I.1-8 MDR and IVDR) and design of software (Annex I.17 MDR and Annex I.16 IVDR are the most important). These contain requirements specifically for

- Software risk management in design;
- State of the art design taking into account the principles of development life cycle, risk management, including information security, verification and validation;
- Usability aspects for mobile use;
- Provision by the manufacturer of minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

At present there are no harmonised standards for GSPRs 17 MDR and 16 IVDR yet. MDCG 2019-16 on Cybersecurity for medical devices contains a list of standards considered relevant by the MDCG.

[137] Blue Guide 2016, section 5.1
[138] Blue Guide 2016, p. 3

3.14.2 Exceptions to conformity assessment

Exceptions to conformity assessment under the default procedure of articles 52 MDR and 48 IVDR are the following devices:

- In-house produced devices under article 5 (5) MDR or IVDR, which are to devices manufactured and used only within health institutions established in the Union. Many health institutions develop their own AI systems for clinical use in-house. These devices may therefore be in scope of the definition of AI system under the draft AI Act and in-house produced device under the MDR and IVDR.
- Devices for clinical investigation/performance studies under article 62 and further MDR/article 57 IVDR are devices applied to patients in a clinical trial or performance studies in scope of the clinical trial / performance studies provisions of the MDR / IVDR. Clinical investigation and performance studies are intended to provide the clinical data or performance data needed for the device to have sufficient clinical / performance data to for a conformity assessment. Highest risk devices must undergo clinical investigation or performance studies under the MDR as a default option.[139] Since the draft AI Act makes no exception for devices in clinical trials or performance studies, these devices must be considered at least potentially in scope of the draft AI Act.
- Custom made devices in the meaning of article 2 (3) MDR, which concerns devices specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and intended for the sole use of a particular patient exclusively to meet their individual conditions and needs. The IVDR does not include a custom-made devices regime. It is not excluded that an AI system would be developed for a specific patient under a prescription from a qualified professional, e.g. a patient-specific algorithm based on the patient's unique DNA sequence[140], although it would be more likely that in practice an AI system would be deployed that is not built patient specific but is trained for the specific patient. The guidance on custom-made devices does not discuss the possibility of software devices being custom-made, but does not exclude this option either. Given the largely theoretical nature of custom-made devices qualifying as an AI system we have not further explored how the custom-made devices regime under the MDR would dovetail with the draft AI Act.

While in-house produced devices and devices for clinical investigation or performance studies comprise exception categories under the MDR and IVDR, they are nevertheless very important from a clinical research perspective. In-house produced devices are often indicated for niche indications for which no commercial solution is available in the market or for which an alternative commercial solution does not deliver sufficiently specific performance for the patient group concerned. If these regimes do not dovetail with the draft AI Act seamlessly, this may have a disproportionate impact on a specific group of patients or frustrate clinical research.

3.14.3 Cybersecurity

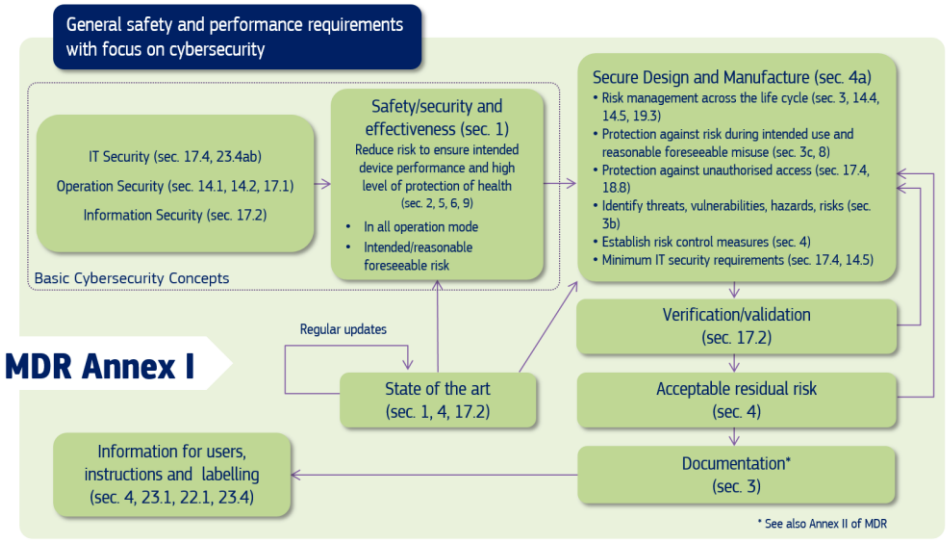
The GSPRs in Annex I MDR and IVDR address cybersecurity in very general terms. The MDCG has however provided guidance in MDCG 2019-16 Guidance on Cybersecurity for medical devices on how

[139] Article 61 (4) MDR

[140] As would be required for a custom-made device, see MDCG 2021-23. This would make an AI system trained for a specific patient more of a patient matched (see MDCG 2021-23, p. 3), or to be more precise 'patient matching' device rather than a an AI system that was developed as a one-off system to the specifics of the given patient. Patient-matched devices are, as is explained in MCGD 2021-23, not custom made devices but rather 'normal' devices.

to fulfil all the relevant essential requirements of Annex I to the MDR and IVDR with regard to cybersecurity.

The cybersecurity requirements in Annex I MDR can be graphically summarised as follows[141]:



The requirements in the IVDR are identical.

These requirements tie into the MDR and IVDR requirements for post market surveillance and requirements regarding privacy and confidentiality of data associated with the use of devices that may be outside the scope of the MDR and IVDR but are subject to other legislations, such as the GDPR.

The AI Act provides for additional requirements in chapter 2 by requiring that an AI system is resilient against malicious actions that may compromise the security of the AI system and result in harmful or otherwise undesirable behaviour. However, these are risks are already addressed under the MDR and IVDR, as can be seen in the above graphic from MDCG 2019-16 regarding cybersecurity of medical devices. The MDR and IVDR cybersecurity requirements have been defined in a technology neutral way, so they also apply to AI systems and may be made more specific by harmonised standards in the field of AI system security, or Common Specifications.

By adding security requirements under the AI Act without regard to whether these have already been addressed under product specific regulation, an AI system in scope of the AI Act and the MDR/IVDR that processes personal data concerning health (which will be the rule for healthcare AI systems) must meet security obligations under three different sets of cyber security requirements:

- privacy and security by design under the GDPR,
- cybersecurity under the MDR/IVDR and, additionally
- security requirements under the AI Act.

[141] MDCG 2019-16, p. 5

4. Consequences

4.1 Is the draft AI Act fit to regulate AI in Health care?

In the previous chapters we investigated the interoperability of the draft AI Act with other applicable legal systems and the potential overlap or conflicts between the draft AI Act and MDR and IVDR.

We have shown the consequences extensively in chapter 3. It leads us to the conclusion that there seems to be no legal gap regarding the safe use of AI in health care in the Netherlands, that the European market for innovative AI solutions in health care will become too unattractive and possibly leads to shifts of companies to other areas. Furthermore, we predict that overregulation as proposed in the draft AI Act will lead to infringements of the patients' autonomy and discretion of the health caretaker.

However, this doesn't mean there is no reason to aim for better regulation of the use of AI in health care. The use of AI in healthcare can have severe consequences in relation to human dignity and patients autonomy. Think of AI systems used to select gender of embryos,[142] AI systems to determine if a patient is in pain[143] or the use of robots like Pepper in bad news consultations.[144]

Another well-known phenomenon in medicine, the lack of trials on female patients [145], may be copied in AI systems.[146] [147] Besides these issues, the socio-economic reality needs as well to be taken into account: does the use of AI in triaging for instance lead to *help* people in getting the right care at the right moment or does it *prevent* it?[148] [149]

In addition, one could argue that modernization in health care caused by the use of AI in health care calls for likewise modernization of our patients' rights. [150] [151]

However, these fundamental issues in health care seem not to be addressed by the draft AI Act. In health care, the draft AI Act will lead to extensive paperwork on the AI systems but leaves the fundamental and ethical questions in this specific domain unanswered. We believe these issues should be addressed for AI systems deployed in a health care setting, regardless of the overlap model chosen, such as specific user requirements imposed under the AI Act.

This leads us to the conclusion that regarding the health care sector, in our view the current draft AI Act has no proper legal foundation seen from the proportionality and subsidiarity principles. This is not caused by the object of regulation, the use of AI systems, but by the choice to design the legislation

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[142] Krgah, M. and Karstof, H. 'Embryo selection with artificial intelligence: how to evaluate and compare methods?' J Assist Reprod Genet 38, 1675–1689 (2021). https://doi.org/10.1007/s10815-021-02254-6

[143] Giordiano, J. 'Pain, Neurotechnology, and the Treatment-enhancement Debate' 2011, < https://www.practicalpainmanagement.com/resources/ethics/pain-neurotechnology-treatment-enhancement-debate >

[144] Groenewoud, Z. cs. 'Pepper-robot voert slechtnieuwsgesprekken. Een interdisciplinair onderzoek naar het inzetten van Pepper-robots ter ondersteuning van artsen bij slechtnieuwsgesprekken met patiënten.' thesis Amsterdam University students, 2021.

[145] Jackson, G. 'The female problem: how male bias in medical trials ruined womens'health.'The Guardian, 2019, < https://www.theguardian.com/lifeandstyle/2019/nov/13/the-female-problem-male-bias-in-medical-trials >

[146] Panch T., Mattie H and Celi, L. The "inconvenient truth" about AI in healthcare, Nature NPJ (77) 2019, < https://www.nature.com/articles/s41746-019-0155-4 >

[147] Perez, C. 'Invisible women. Exposing data bias in a world designed for men', Vintage, London, 2019.

[148] Eubanks, V. 'Automating inequality. How high-tech tools profile, police and punish the poor.' Picador, 2019.

[149] See the recommendations of the regulatory sandbox by the Care Quality Commission UK, Getting to the right care in the right way – digital triage in health services A report with recommendations from CQC's first regulatory sandbox.

[150] Robbins, R, and Brodwin, E. 'An invisible hand.: Patients aren't being told about the AI systems advising their care.' Statnews, 2020. < https://www.statnews.com/2020/07/15/artificial-intelligence-patient-consent-hospitals/ >

[151] Cohen, I. Glenn, Informed Consent and Medical Artificial Intelligence: What to Tell the Patient? (May 1, 2020). Georgetown Law Journal, Vol. 108, pp.1425-1469, 2020, Harvard Public Law Working Paper No. 20-03, Available at SSRN: https://ssrn.com/abstract=3529576 or http://dx.doi.org/10.2139/ssrn.3529576

based on product safety and the choice for omnibus legislation instead of domain specific regulatory measures.

In this legal analysis we have elaborated on these observations. In addition, we want to illustrate how the draft AI Act would interact with our current legal systems. In chapter 4.3 we will explain how the current proposal raises questions on proportionality and subsidiarity. In section 4.3 we will explain how the current proposal raises questions on proportionality and subsidiarity.

4.2 Illustration of the practical consequences of the draft AI Act in relation to MDR/IVDR and national health law

To demonstrate the outcome of the previous chapters we will illustrate the consequences of the draft AI Act by the elaboration of a fictional case concerning the use of AI in a Dutch hospital.

Example

A start-up company has developed an innovative software with smart algorithms that uses patient data to search improved treatment methods for patients with brain injury. With the output of this software healthcare providers can quickly find out where the injury is located and treat the injury more efficiently and effectively. Therefore, the healthcare provider can prevent the brain injury from getting worse and there is higher chance that the patient recovers more quickly from a brain injury. The start-up company wants to cooperate with several hospitals and want to use the patient data from the cooperating hospitals to use it for scientific research and to improve the algorithm.

Before the draft AI Act takes effect, the start-up company has to comply with the MDR and the GDPR. Firstly, the GDPR. The start-up company has to carry out a Data Protection Impact Assessment (DPIA) to ensure that the data exchanges comply with the GDPR. Possible risks must be identified, and measures must be taken.

Secondly the MDR. Since the software can be classified as a medical software device, the software must undergo the conformity assessment procedure to obtain a CE certificate from the Notified Body. Therefore, the start-up must implement a risk management system, a quality management system and compose technical documentation. In addition, the start-up company must go through a clinical evaluation to ensure that the product is safe for the user. This evaluation also entails the security of the software. Also, the possible risks must be identified, and measures must be taken to prevent those risks. After the medical software device has obtained the CE certification, the medical software must be registered in the EUDAMED. The start-up company also has the obligation to conduct a Post Market Surveillance regularly, which means that the start-up company must monitor the safety and the performance of the software. The start-up company must also keep track of the side effects and risks of the use of its software, investigate them and take action if necessary.

If the draft AI Act enters into force as it is in this form, the start-up company still has to undertake the required steps from the GDPR and the MDR as mentioned above. At the same time the start-up company must also comply with the requirements from the draft AI Act. Just like the MDR, the software must obtain another CE certification by undergoing the conformity assessment procedure in accordance with the draft AI Act. Therefore, the software must be developed and designed in such way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity and perform consistently in those respects throughout their lifestyle. In addition, the software must be designed and developed in such a way that the operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. There must also be an appropriate human-machine interface tools available for the user during the use of the software. The start-up company must also implement a risk management system, a quality management system and draw up a technical documentation under the draft AI Act. The start-up company must also register

the software in a European database for stand-alone high-risk AI systems and conduct Post Market Monitoring regularly to evaluate the continuous compliance of the software with the draft AI Act.

Seen from the legal relation between patient and healthcare provider such as the hospital and the doctor, the healthcare provider has several obligations towards the patient. Healthcare providers have to follow the rules established in the Medical Treatment Act, GDPR, MDR and numerous professional standards and protocols. For instance, the healthcare provider must be sure that the software has a CE marking and complies with the Union and national law. The healthcare provider must carefully inform the patient, in the language that the patient can understand, about the treatment with the software and any consequences of the treatment. In principle the healthcare provider cannot start the treatment if the patient does not give his consent. The healthcare provider also has the duty of confidentiality in respect of everything that he learns about the patient during the course of his work as healthcare provider. This means that the healthcare provider in principle cannot share patient data with the start-up company without the prior consent of the patient. The healthcare provider is liable to the patient for the medical treatment. This means that the healthcare provider can be held liable under civil law and under disciplinary law (and in extreme cases under criminal law) if the patient is harmed by using the software during the medical treatment.

In civil law the patient can hold the healthcare provider liable for the damage he has suffered. The patient is often assisted by a legal counsel in these matters, given the complexity of medical issues and the emotional involvement of the patient. Under certain circumstances, the patient can also hold the start-up company liable for the damage if the damage was caused by a defect in the software that was already present when the software was marketed.

The purpose of disciplinary law is to monitor and promote the quality of professional practice. The disciplinary judge assesses whether the care provider has exercised the care that he should have exercised in his capacity towards the patient and his relatives. The disciplinary judge also assesses whether the care provider has acted in accordance with what is expected of a proper professional practitioner. The patient, the representative or the Health and Youth care inspectorate can submit a case to the disciplinary court. The healthcare provider can get a warning, a reprimand, a fine, or (temporarily or partially) suspended from his work.

If the patient believes that the healthcare provider has committed a criminal offence against him, then he can make a report to the police. The public prosecutor decides whether or not to start criminal proceedings against the healthcare provider. The punishment can differ from no punishment to a suspended prison sentence of several months or community service. All procedures can take place at the same time.

However, under the draft AI Act the healthcare providers will be on top of that as well considered to be ‘users’ of high-risk AI systems (‘any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity). Without prejudice to the abovementioned obligations, the healthcare providers have additional duties.

The healthcare provider must use the software in accordance with the instruction of use accompanying the software. If the healthcare provider has control over the input data, then he must make sure that the input data is relevant for the intended purpose of the software. The healthcare provider must also monitor the operation of the software. In addition, the healthcare provider must inform the start-up company and discontinue the use of the software if the healthcare provider has reasons to believe that the use in accordance with the instruction of use may lead to a risk or when he identified any serious incidents or any malfunctioning. If the healthcare provider could not reach the start-up company, then he must report this to the national market surveillance authority where the incident has occurred. The healthcare provider is obliged to keep logs that is automatic generated by the software as far as he has the logs under his control. The logs must be kept for the period that is appropriate for the intended

purpose and to the extend required by Union or national law. The healthcare provider must also carry out a DPIA with regard to the use of the software.

4.3 Legal Basis Draft AI Act

Given the problems or unwanted consequences stated above, it is necessary to observe if the core of the draft AI Act is in line with the competence of the EU.

The EC explains that the legal basis for the proposal is founded upon Article 114 of the Treaty on the Functioning of the European Union (TFEU), which provides for the adoption of measures to ensures the establishment and functioning of the internal market. Since some member states are already considering national rules to ensure that AI is safe and developed and used in compliance with fundamental rights obligations, the EC foresees problems for the internal market (explanatory memorandum, 2.1). The draft AI act is meant to solve problems of fragmentation of the internal market and diminishment of legal certainty. The framework of the draft AI act with common mandatory requirements applicable to the design and development of certain AI-systems and the ex-post controls are seen to fit as solutions (explanatory memorandum, 2.) Furthermore, the EC considers Article 16 of the TFEU the second foundation on which the draft AI Act is build regarding the rules on the protection of individuals as laid down in Article 5, 1, sub d, draft AI Act (real-time remote biometric identification).

It is important to investigate how the draft AI Act interacts with the regulatory competences of member states. Especially since there is no history of previous attempts to regulate AI systems by other less severe measures, such as soft law or a Directive, the choice for a general (instead of domain specific) Regulation needs a critical view regarding the solution the EC proposes.

4.3.1 Subsidiarity principle

The EC states the draft AI Act is in accordance with the subsidiarity principle (Article 5(3) of the TEU). The subsidiarity principle means that there are three preconditions for intervention: (a) the area concerned does not fall within the Union's exclusive competence (i.e. non-exclusive competence); (b) the objectives of the proposed action cannot be sufficiently achieved by the Member States (i.e. necessity); (c) the action can therefore, by reason of its scale or effects, be implemented more successfully by the Union (i.e. added value).[152]

Though the safety of products and safe use of AI can be considered as goals that can be reached better by the Union then by Member States, it can be problematic if the EU uses its competence not carefully. One could argue that the subsidiarity principle means as well that EU intervention is not appropriate if it mostly adds legal unclarity. As we have shown, the draft AI Act as well interferes with the national competence to the organization of healthcare.

We therefore conclude that it is questionable if the subsidiarity principle is met with the current approach as is laid down in the draft AI Act.

4.3.2 Proportionality principle

By extracting the technology AI as the instrument that needs to be regulated, the draft AI Act inevitably suffers of the problem that many several different legal international and national systems will be confronted with this draft AI Act. The justification for this choice is not very clear. It will lead to very complicated legal and societal questions and conflicts with national legal systems.

The use of AI in agriculture (agricultural law,) evaluating staff (employment law), or the use of AI in health care (health law) has similarities as much as differences. On one hand, the draft AI Act uses the

[152] https://www.europarl.europa.eu/factsheets/en/sheet/7/the-principle-of-subsidiarity

technology as object of regulation, on the other hand the draft AI Act regulates the use of the technology in specific sectors. This seems problematic from the proportionality point of view.

Unclear is as well how the draft AI Act interacts with the Machinery directive and MDR regarding the use of robots and robotics in health care for care taking or to enhance human functions by using wearable robots like exoskeletons. As Fosch Villaronga states the current mosaic of existing regulations of healthcare robots needs a thorough analyses *before* new regulation is developed. For instance, not all healthcare robots might be considered 'medical devices,' and maybe new emerging rights such as 'the right to a meaningful contact' developed by the Parliamentary Assembly of the Council of Europe should have to be realized.[153]

4.4 Conclusion

Though it seems clear that in general, the use of AI in health care needs to be better regulated, it can be said that the choice of the EC in the current general and broad proposal, may not be the best solution for Dutch healthcare. Moreover, we can raise the question what exactly the problem is the proposal tries to solve in health care. It seems to disrespect existing frameworks in health law and it may weaken the legislating powers of the Dutch legislator because it is uncertain what the draft AI Act means for the current sovereign competence to make other necessary rules on the use of AI in Dutch health care. An issue that is also striking in other areas such as in administrative law or criminal law.[154]

As we have shown thoroughly in chapters 2 and 3 of the MDR/IVDR and the draft AI Act are not compatible. We may even conclude that regarding the use of AI in health care, there is no proof of a legal vacuum that needs to be filled in the first place. One could even say that the draft AI Act violates the subsidiarity principle as well as the proportionality principle.

[153] E. Fosch Villaronga, Regulating healthcare robot and AI technologies, 2019. https://data-en-maatschappij.ai/publicaties/paper-regulating-healthcare-robot-and-ai-technologies

[154] Ibid Veale & Zuiderveen Borgesius

5. Advice on concrete amendments

5.1 Our advice

Given the inconsistencies between AI Act and the MDR/IVDR and the serious consequences mentioned in chapter 4 and the resulting questions on the competence of the EU to regulate by this proposal, we advise to ensure that these regulations dovetail better. The AI Act, as horizontal regulation, intends to overlap with and dovetail into product specific regulations well and with as little issues as possible. As we have explained, this goal is not achieved at all. For this reason, the dovetail between the AI Act and the MDR/IVDR could be managed a lot better. There are several options:

- Exclude AI-systems that fall under the MDR /IVDR from the scope of the draft AI Act based on the l*ex specialis* principle that AI systems that are devices in scope of MDR/IVDR are already adequately regulated under these product 50specific regulations, as discussed in relation to the EMC Directive model. Exclude AI-systems that fall under the MDR /IVDR from the scope of the draft AI Act based on the l*ex specialis* principle that AI systems that are devices in scope of MDR/IVDR are already adequately regulated under these product specific regulations, as discussed in relation to the EMC Directive model. This could be a way forward that is supported by existing NLF acquis and it is a solution already provided for in the MDR/IVDR with respect to other horizontal legislation such as the EMC Directive;
- Amend the overlap mechanism to align with the so-called Machinery Directive model of overlap. According to the AI Act, this is also the mechanism that was intended to be achieved by the Commission when drafting the AI Act, so this could be a way forward within existing MDR/IVDR structures and, moreover, would be commensurate with how the AI Act envisages its interface model with product specific regulation. This solution however does not solve other problems flagged in relation to overlapping application of the MDR/IVDR and the AI Act, such as differing definitions of NLF concepts between the MDR/IVDR on the one hand and the AI Act on the other hand;
- remove the overlap mechanism altogether with separate CE marking under the AI Act and thr MDR/IVDR respectively in accordance with the so-called RoHS/RED model, but allow for one single declaration of conformity for the product, thus declaring conformity to both the AI Act and the MDR or IVDR.

If this is not desirable, we advise to change the ranking of AI-systems that fall under the MDR/IVDR and used in health care as high-risk AI Systems. The same applies for systems that fall under the MDR/IVDR and used to allocate patients to the most suitable healthcare providers [155], possibly falling under Article 5, sub c in Annex III (AI systems intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by firefighters and medical aid). The same applies for systems that fall under the MDR/IVDR and used to allocate patients to the most suitable healthcare providers,[156] possibly falling under Article 5, sub c in Annex III (AI systems intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by firefighters and medical aid). We refer in this respect to the solution proposed in consideration 38 on AI-systems specifically intended to be used in for administrative proceedings by

[155] Like the EEG cap designed with crowdfunding by researchers of Amsterdam Neuroscience, Couthino, J. and Potters, W. for reliable prehospital screening methods in the ambulance to identify stroke patients eligible for endovascular treatment. < https://www.amsterdamumc.org/web/file?uuid=5f3dc3cc-ee42-44ff-9171-cdbbb0502b11&owner=a74723e4-a91d-4fe3-859b-fc7f4c1f86a2&contentid=12399 >

[156] Like the EEG cap designed with crowdfunding by researchers of Amsterdam Neuroscience, Couthino, J. and Potters, W. for reliable prehospital screening methods in the ambulance to identify stroke patients eligible for endovascular treatment. < https://www.amsterdamumc.org/web/file?uuid=5f3dc3cc-ee42-44ff-9171-cdbbb0502b11&owner=a74723e4-a91d-4fe3-859b-fc7f4c1f86a2&contentid=12399 >

tax and customs authorities should not be considered high-risk used by law enforcement authorities for the purpose of specific actions. We refer in this respect to the solution proposed in consideration 38 of the draft AI Act on AI-systems specifically intended to be used in for administrative proceedings by tax and customs authorities should not be considered high-risk used by law enforcement authorities for the purpose of specific actions.

Finally, we have pointed out a number of points of concern in this advice that we believe should be addressed for AI systems deployed in a healthcare setting, regardless of the overlap model chosen, such as specific user requirements imposed under the AI Act.

We believe that the nexus between article 5 (5) MDR/IVDR and conformity assessment under AI Act requirements should be a specific member state concern that is looked at in more detail because of the influence this may have on AI systems developed and deployed within health institutions.

In the current drafting of the AI Act health institutions developing AI systems within the exemptions to conformity assessment under the MDR and IVDR would nevertheless be obliged to undergo conformity assessment by a notified body under the AI Act, which has the potential of making in-house production and deployment of AI systems by health institutions prohibitively burdensome. This may have a detrimental effect on AI development and scientific progress in health institutions.

Parkstraat 20, 2514 JK Den Haag **T** +31(0)70 2172066 **E** info@hooghiemstra-en-partners.nl
ING Bank NL49INGB0008938076 **www**.hooghiemstra-en-partners.nl **KvK** 73390356 **BTW** 8595.06.447.B01