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Bundesministerium für Wirtschaft und Klimaschutz

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11019 Berlin

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11 June 2024

Exemplary application of the EU AI Act to medical device use cases

Dear Mr. Koehler,

In response to the stakeholder dialogue conducted by your ministry on March 25th, 2024, we would like to present a medical device industry perspective in applying the EU AI Act to specific medical devices.

The four use cases attached have been provided by Ada Health GmbH, CADS GmbH, Carl Zeiss Meditec AG and Siemens Healthineers AG (the content of each use case is the sole responsibility of its providing company). These use cases cover a diverse range of medical device applications such as AI based software to diagnose (segmentation, classification and volume determination), to predict disease progression, to guide and to monitor therapies in the field of bones, brain and lung images as well as AI based symptom assessment. All use cases are subject to the Medical Device Regulation (MDR) or the In-vitro-Diagnostic Medical Device Regulation (IVDR).

While the submitted use cases differ with respect on how AI is specifically integrated in the presented medical devices, all use cases reflect the need for further details as well as more specific guidelines on the intention and interpretation of the EU AI Act in particular with respect to the following aspects:

Article 6: Classification Rules for High-Risk AI Systems

All submitted use cases highlight the need for more precise specification regarding the classification of an AI system that is intended to be used as a safety component of a product, or that itself is a product as a high-risk system.

Our current understanding of the systematic categorization of High-Risk AI Systems is summarized as follows:

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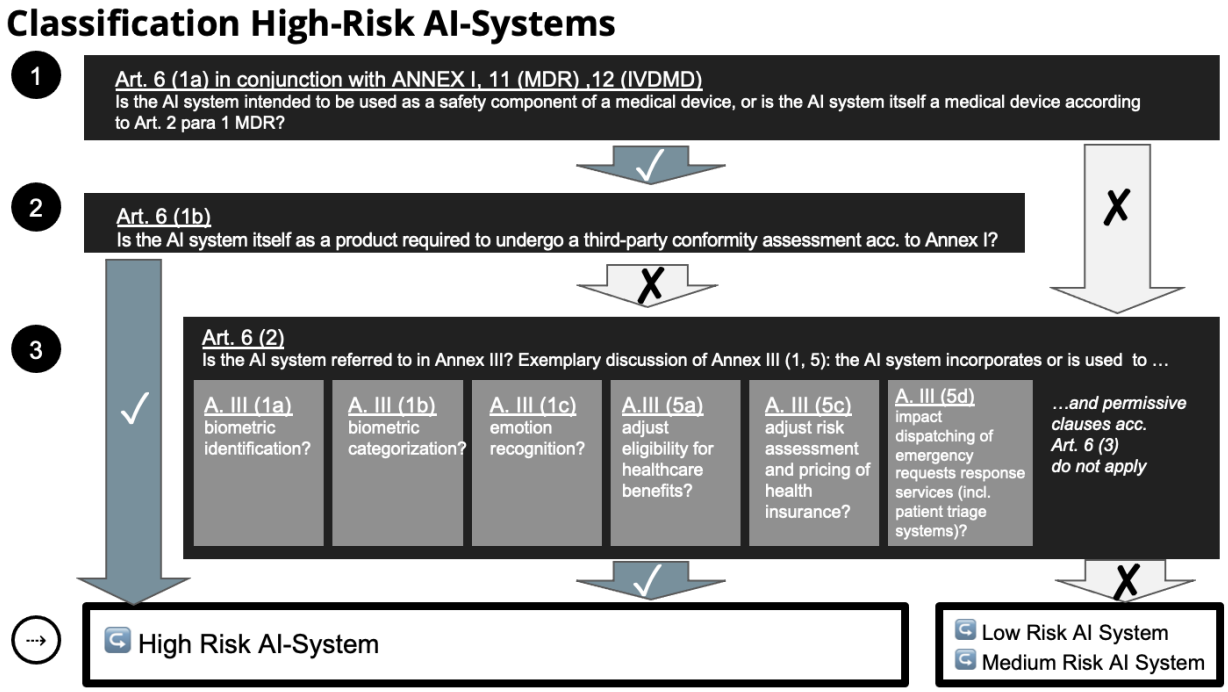

Chart 1: Schematic representation of the classification of High-Risk AI Systems acc. to EU AI Act

Beyond the logic of classification, defining criteria such as

> ***'the AI System is intended to improve the result of a previously completed human activity'*** Article 6 (3 b) EU AI Act

or

> ***'AI systems intended to be used for the recruitment or selection of natural persons, in particular to place targeted job advertisements, to analyse and filter job applications, and to evaluate candidates'*** Annex III 4 (a) EU AI Act

or

> ***'AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance'*** Annex III 5 (c) EU AI Act

should be further specified, too. For instance:

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1. Is an AI system to be classified as high-risk in case it is categorized as a medical device of risk class I acc. to MDR with an intended purpose of vision monitoring and that is used by an airline company for recruitment and selection of pilots (intended purpose of vision monitoring does not exclude explicitly the use case vision monitoring in pilots)?
2. Does any intended function that determines the risk of a disease or therapy progression drive the classification of the medical device as a high-risk AI system in case a private health insurance company in Europe uses the outcome of the medical device to adjust its insurance premiums?

In summary, we received several requests with respect to technical definitions as well as interpretation of the AIA regarding the categorization of high-risk AI systems. Further, guidance is needed to facilitate the intended implementation.

Article 9: Risk Management System

All submitted use cases emphasize the need for more precise specification regarding the addressed risk according to Article 9 EU AI Act. As for medical devices, the risk management with respect to the intended purpose of the medical device is already addressed and regulated under MDR/IVDR. It should be confirmed that applying the EU AI Act's requirements towards a risk management system to a medical device needs to be done in accordance with the medical device's intended purpose (of which the AI system may only be a part).

Article 14: Human Oversight

The application of Article 14 EU AI Act to the submitted use cases leads to manifold requests for more precise specification of the clause. Here, also the general intention of the regulation is not well understood. Requests of the industry that our associations received addressed the question whether Art. 14 EU AI Act is intended to determine that each individual use or manifestation of the AI system, or its component, should be subject to human oversight. In addition, provided definitions such as

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> ***"High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are <u>in use</u>"*** Article 14 (1) EU AI Act

lack specification with respect to the addressed situation. For instance, if an AI system analyzes images before experts can access a patient file, should human oversight take place at this stage in time (human oversight to the technical process) or once the results of the AI system are available for expert review (human oversight to the results). If the AI system is built in a way that the results can be reviewed by an expert, is this already fulfilling the passus *"effectively overseen by natural persons during the period in which they are in use"*? Moreover, certain interruptions of the technical processes of AI systems might lead to unintended results and pose a security risk itself. In addition, typical implementations of an AI system or its components, for instance as a mobile app, do not allow for human-machine interface tools that are addressed by experts.

Again, more specific guidance including technical definitions with respect to the application of human oversight will be highly appreciated.

The undersigned associations would like to thank you for the opportunity to address the above points and appeal to the German Federal Government to address the existing challenges in implementing the EU AI Act as soon as possible and to develop solutions in agreement with the proposed mitigation measures.

As regulatory compliance is of uttermost relevance for the future of our represented industry, we are committed to being a proactive partner and look forward to supporting this innovative framework policy.

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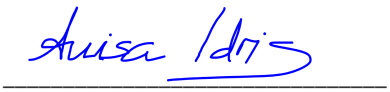
Sincerely yours,



Anisa Idris

Member of the board

Signed on behalf of the associations listed on the letterhead

Appendix: submitted use cases of the EU AI Act

1. Ada Health GmbH: Symptom assessment
2. CADS GmbH: AI-driven segmentation software
3. Carl Zeiss Meditec AG: Segmentation and classification of brain areas (including cerebrospinal fluid) and their volume determination
4. Siemens Healthineers AG: AI Rad Companion (Pulmonary)

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Use Case:	Ada Health App

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A Use Case

1. Intended Purpose

The Ada Health App is an AI-based health assessment software application intended to provide personal health insights and guidance. The insights and guidance provided include an overview of possible conditions, an estimated likelihood of each condition, and navigation to the appropriate level of care.

After an assessment, the user can share their results with healthcare providers, who may consider this information for clinical decision-making.

Ada Health App is not a substitute for advice from a healthcare professional and does not provide a final medical diagnosis.

The symptom assessment helps users understand possible causes for their symptoms, there is no limitation in place for specific indications. The Ada Health library contains information about thousands of medical conditions.

The Ada Health App can be downloaded from the App Store of Google Play Store and used on a smartphone.

2. Intended Users

The Ada Health App has been designed for people at age 16 or above, but its underlying medical engine has been developed with all age groups in mind. The app is designed for everyone to use – no medical training is required. To use the Ada Health App safely, the user needs to be able to read at approximately the level of a 13–15-year-old. People under the age of 16 are not allowed to use the Ada Health App themselves, but their legal guardian can complete an assessment on their behalf.

If a user is experiencing a medical emergency, he or she should not use the Ada Health App.

3. Device overview

The Ada Health App is an AI-based health assessment app intended to provide personal health insights and guidance based on your reported health and symptoms.

The app asks health questions in a conversational style, similar to a chatbot.

In particular, the Ada Health App asks users demographic (onboarding) questions that are followed by questions regarding the health concern (symptoms) they are concerned about. The app then guides them through a series of questions. The responses help the Ada Health App identify possible causes for health concerns.

When the assessment is complete, the user receives the results. The assessment results include a list of the most likely causes and a recommendation for the level of care the user should seek. Users can download assessment results as a PDF document.

Overall Advice Levels	Condition-specific Advice Levels
If you think you have this condition, you can probably manage your symptoms safely at home. However, if you are worried, if your symptoms persist or get worse, or if you notice new symptoms, you should seek advice from a medical professional.	Can usually be managed at home
People with similar symptoms can usually manage their symptoms safely at home. You could also seek advice by visiting or contacting your local pharmacy. If your symptoms persist longer than expected, if they get worse, or if you notice new symptoms, you should consult a doctor for further assessment and advice.	Can usually be managed at home
People with similar symptoms may require urgent medical care. If you think this is an urgent problem you should seek advice from a doctor straight away.	Seek Medical Advice
People with similar symptoms may require prompt medical assessment and care. You should seek advice from a doctor within the next few hours.	Seek Medical Advice
People with similar symptoms do not usually require urgent medical care. You should seek advice from a doctor though, within the next 2-3 days. If your symptoms get worse, or if you notice new symptoms, you may need to consult a doctor sooner.	Seek Medical Advice
People with similar symptoms do not usually require urgent medical care. You should seek advice from a doctor, though it is probably okay for this to be a routine appointment. If your symptoms get worse, or if you notice new symptoms, you may need to consult a doctor sooner.	Seek Medical Advice
People with similar symptoms may require emergency care. If you think this is an emergency you should go to an emergency department without delay.	Seek emergency care
People with similar symptoms may require emergency care. If you think this is an emergency the safest thing to do is call an ambulance.	Seek emergency care

Caution! The Ada Health App will immediately stop the assessment if a user provides information that indicates an emergency situation or condition. This includes suicidal ideation and chest pain that may indicate a heart attack. The app will inform users that this is a serious situation and that he or she needs to seek medical attention right away. It is possible to continue with the assessment, if the user chooses to.

4. User safety

The Ada Health App should not be used as a substitute for advice from a healthcare professional and does not provide a final medical diagnosis. Thus, users are to seek healthcare professional advice in the following circumstances:

Precautions

- The assessment report is produced based on the information that users provide. User provided answers should be true and accurate. The Ada Health App works best when the symptoms that are most worrying to the user are entered, such as the ones that have appeared most recently or most rapidly. Inaccurate or false answers can lead to the delivery of an assessment report that is not suitable for users (i.e. inaccurate advice levels). If users choose to follow these inaccurate advice levels, the efficacy of the medical device is no longer ensured.
- When accessing the Ada Health App from a smartphone, it should be ensured that a supported operating system which is up to date with the latest stable release and security patches is used.

Safety warnings

- Do not use the Ada Health App in an emergency situation. In the case of an emergency, contact your local medical emergency services.
- Do not use the Ada Health App as a substitute for the advice of a healthcare professional.
- If users' symptoms get worse during an assessment, interrupt the assessment and consult a healthcare professional.
- The Ada Health App is not a diagnostic tool. If users are concerned about any symptoms, please consult a healthcare professional regardless of the outcome of the assessment.
- Do not wait to seek medical care, if users are concerned about their health. Waiting may lead to delayed care and cause deterioration of health status.

Side effects

- Use of digital health tools may be related to increased health anxiety, particularly if the conditions suggested to the user include distressing or sensitive conditions.
- Use of digital health tools may be related to increased self-surveillance and normalisation of health-seeking behaviour.

Residual Risk

- The Ada Health App provides a list of conditions that it has identified as possible causes for symptoms. This is not an exhaustive list. You may have a condition that is not suggested. Users are asked to consult a healthcare professional if they are concerned about their health status.

- The Ada Health App may suggest sensitive or upsetting conditions in the assessment report. Users should not complete an assessment, if they do not wish to learn information that may cause distress or anxiety.

5. Expected clinical benefit

The Ada Health App provides timely and accurate symptom assessments for the user by generating a list of possible causes and suggestions for the appropriate level of care. Access to this kind of personalised health information can increase the user's health awareness and peace of mind. The app can also facilitate communication, interaction and care navigation with the user's healthcare provider.

6. Performance characteristics of the device

The performance of the device depends on the underlying performance of a software module of the Ada Health App that includes, among other components, the medical reasoning engine. The performance of the module has been shown to be state-of-the-art in testing against medical doctors and other on-market symptom assessment applications. Every update of the module is tested against a large number of clinical case scenarios to ensure that performance is always maintained within defined acceptance criteria for condition suggestion accuracy and for the proportion of relatively lenient or over-cautious advice about onward care. The results of the accuracy, leniency, and over-cautiousness tests must pass certain criteria (within defined thresholds with a confidence of >95%) before a new software module is approved for release.

B. Executive Summary

The following remarks to the AIA (Artificial Intelligence Act, Version: P9_TA (2024) 0138) emerged by applying this regulation to the use case Ada Health App. The defining features of the underlying use case are: An AI system being a component to a medical device of MDR class IIa, intended to provide personal health insights and guidance to lay persons with newly emerged or continuing present health concerns. The insights and guidance provided by Ada Health App include an overview of possible conditions, an estimated likelihood of each condition, and navigation to the appropriate level of care.

A significant proportion of the requirements laid out for high-risk AI in the AIA are targeted at machine learning techniques (such as governance of training, testing & validation data). As medical devices are just released and in use by the public, once the medical device operates in a static state, most of the regulation does not address medical devices appropriately. Therefore, guidance, if not, a categorization of requirements addressing high-risk AI for dynamic and/or static AI-based medical devices would be very useful for implementing AIA compliance in an efficient and effective manner.

In addition, clarification whether the requested transparency and provision of information to deployers (Article 13) and required human oversight (Article 14) addresses the AI system in general or each use of the AI system itself is needed for compliant implementation.

Finally, please note that an in-depth assessment of the implications of establishing compliance with the AIA can only be fully launched once the harmonized standards have been defined.

C. Detailed Analysis

Chapter I: General Provisions

No.	Chapter	Section	Article
1	I	1	Article 2, No. 8

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
Article 2, No. 8	1: *unclear wording, wording of clause*	8. This regulation does not apply to any research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law. **Testing in real world conditions shall not be covered by that exclusion.** Under MDR a CE mark is not obligatory for clinical investigation but the EU AI act does not reflect this exception.	Under MDR, investigational devices are not considered as being placed on the market, put into service, or made available. Clarification is needed whether article 2 No. 8 "research" includes also clinical studies and user research studies (UXR). Include real world testing under the premise that is transparent to users.

No.	Chapter	Section	Article
1	I	1	Article 3, No. 4

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
Article 3, No. 4	1: *unclear wording, wording of clause*	4. 'deployer' means a **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**; As Ada Health GmbH is providing the Ada Health App in this use case via App stores to lay person for non-professional activity, there is no 'deployer' in this use case.	Clarification provided in the guidance to the AIA that natural persons using AI system in non-professional activities are not deployers and that, in case, results are of the AI system are shared with experts, in this use case, health care professionals such as physicians, they are also not to be understood as deployers as they did not use, nor did they facilitate the use of the Ada Health App in their authority.

Chapter II: Prohibited Artificial Intelligence Practices | No Comment

Chapter III: High-Risk AI System

No.	Chapter	Section	Article
1	III	2	Article 8, No. 2

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
Article 8, No. 2	1: *wording of clauses*	Where a product contains an AI system, to which the requirements of this regulation as well as requirements of the Union harmonisation legislation listed in Section A of Annex I apply, providers shall be responsible for ensuring that their product is fully compliant with all applicable requirements under applicable Union harmonisation legislation. In ensuring the compliance of high-risk AI systems referred to in paragraph 1 with the requirements set out in this Section, and in order to ensure consistency, avoid duplication and minimise additional burdens, providers **shall have a choice of integrating, as appropriate, the necessary testing and reporting processes, information and documentation** they provide with regard to their product into documentation and procedures that already exist and are required under the Union harmonisation legislation listed in Section A of Annex I. The wording “shall have a choice as appropriate” suggests that documentation is to be evaluated, disengaged and provided selectively.	A clarification that a provider is compliant with Art. 9 AIA without further do in case the provided AI system itself is a product for which a third-party conformity assessment has been successfully concluded.

No.	Chapter	Section	Article
1	III	2	Article 13, No. 1

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
Article 13, No. 1-3	1 and 3: *unclear wording / addresses of this regulation*	1. High-risk AI systems shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent to **enable deployers** to interpret a system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured with a view to achieving compliance with the relevant obligations of the provider and deployer set out in Section 3. As described above with respect article 3 No. 4 - the presented use case does not foresee a deployer. If there is no deployer intended by the provider, are this article and the following article 13-15 still to be followed for theoretical feasible deployers?	Provide guidance that this article 13 is just to be followed in case a deployer is contracted by an provider for in a capacity as described by article 3 No. 4. Provide guidance that the provisions for the Instruction for Use acc. to art. 13 (3) are not to be understood as a general obligation but an obligation in case a deployer exists.

No.	Chapter	Section	Article
1	III	2	Article 14, No. 1-3

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
Article 14, No. 1	1: *unclear reference*	1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen **by natural persons** during the period in which they are **in use**. Art. 14 (1) AIA posits the design and development of high-risk AI systems to include appropriate human-machine interface tools, but does not specify whether natural persons using the human-machine interface tools should be employees of the providers or users or deployers. In addition, Art. 14 (1) postulates that human-machine interface tools should be present once the high-risk AI system is in 'use', without specifying what is to be understood with this reference. The presented use case addresses a scenario of Ada Health App being used by lay people on the personal mobile. Should this clause be understood that providers should in theory be able to monitor each symptom assessment and provide appropriate human-machine-interface tools for correction? As medical device are required to exhibit a positive risk-benefit ratio and to provide all adequate risk mitigation measures in order to conclude a conformity assessment successfully, providers have put in place measures with adequate effects to human oversight for the use of the high-risk AI system medical device.	A clarification that a provider is compliant with Art. 14 (1) AIA without further do in case the provided AI system itself is a product for which a third-party conformity assessment has been successfully concluded.
Article 14, No. 2	2: *unclear reference*	2. **Human oversight shall aim to prevent or minimise the risks to health, safety or fundamental rights** that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular where such risks persist despite the application	A clarification that a provider is compliant with Art. 14 (2) AIA without further do in case the provided AI system itself is a product for which a third-party conformity assessment has been successfully concluded.

		of other requirements set out in this Section. Ada has put in place several systems to monitor health, safety and other impacts with reference to Ada Health App as a MDR medical class IIa product. These measures are already in place and, of course, include the implemented AI System itself. Further guidance should specify that these measures are sufficient for medical devices in order to establish compliance with AIA.	
Article 14, No. 3	3: *unclear wording, reference*	3. The oversight measures shall be commensurate with the risks, level of autonomy and context of use of the high-risk AI system, and shall be ensured through **either one or both of the following types of measures**: (a) measures identified and built, when technically feasible, into the high-risk AI system by the **provider before** it is placed on the market or put into service; (b) measures identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the deployer.	A clarification that a provider is compliant with Art. 14 (3) AIA without further do in case the provided AI system itself is a product for which a third-party conformity assessment has been successfully concluded.

Chapter IV: Transparency Obligations for Providers and Deployers of Certain AI Systems and GPAI Models | No Comment

Chapter V: General Purpose AI Models | No Comment

Chapter VI: Measures in Support of Innovation | No Comment

Chapter VII: Governance | No Comment

Chapter VIII: EU Database for High-Risk AI Systems | No Comment

Chapter IX: Post-Market Monitoring, Information Sharing, Market Surveillance | No Comment

Chapter X: Codes of Conduct and Guidelines | No Comment

Chapter XI: Delegation of Power and Committee Procedure | No Comment

Chapter XII: Confidentiality and Penalties | No Comment

Chapter XIII: Final Provisions | No Comment

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Use Case:	AI-driven Segmentation Software

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Use Case

This Use Case is about an AI driven segmentation software. An AI model is trained with patient images to be able to segment the bones of the human skull and detect tumor-regions.

The software is intended to be used for segmenting adult human skulls for diagnostic purpose. The software provides a tumor and fracture detection.

The AI model shall also provide a fracture repositioning as well as an implant design with corresponding cutting guides.

Executive Summary

Right now, we have reviewed the requirements for high-risk AI-systems according to chapter III section 2 of the act.

For each requirement we have summarized the respective article and, if applicable, added our comments.

While the basis of the act is quite understandable for an already regulated company, we encountered the need of "best practices". This could be accomplished with technical harmonized standards or with guidance documents.

Detailed Analysis

Scope of the law (application of the AI act)

Within Article 3 of the AI Act, the definition of an AI-System itself is given:

'AI system' means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments;

Questions from our side

Reading this paragraph, we would say this definition only applies to systems which use the output as an input for changing the algorithm "live". This would be the case for an only limited number of systems since most of the training-models will stay static after an integration into the product.

No.	Chapter	Section	Article
REQ-00	*CHAPTER 1 General Provisions*	N/A	Art. 3 (1) 'AI system' means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments;

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
ISS-00	*2 - Lack of definition*	*It is unclear if the definition only applies to AI-models which change during usage by itself.*	*Refactoring of the definition. Clarification*

Classification

According to Article 6 section 1 of the AI Act, the AI-system is classified to have a "high risk" if:

- The AI-System is part of the products listed in Annex 1 of the AI Act, and,
- If the system must have a conformity assessment.

Annex 1, section A Article 11 lists the "medical device regulation 2017/745 which is applicable for our software, thus, the first part of Article 6 section 1 is fulfilled. To be categorized as a "high risk" device, the second part of article 6 section 1 needs to be fulfilled as well. Since the software is higher than Class I according to the medical device regulation, the medical software needs a conformity assessment by a notified body. Therefor the classification "high risk" for the AI-system is given.

Section 2 of Chapter III lists the requirements for high-risk AI-Systems. Requirements may be included in existing processes or documentation.

Fulfillment of requirements Article 8

This is a generic article which states that AI systems with high risk need to fulfill the requirements of section III.

Questions from our side

How's the state of the art defined for AI systems? Are there any norms about minimum requirements for medical image-based classification models available?

Another point is the source of the AI publications that define the state of the art in this field. arXiv.org is a very common source for publication of worldwide active research groups. A major drawback is that this platform is a free distribution service and an open-access archive WITHOUT any peer-reviewing which is obligatory in every scientific journal. Additionally, state of the art is usually shown for a first time at the big conferences (NeurIPS, MICCAI, CVPR among others). Are these proper sources?

On the other hand, if we develop one or multiple AI models for our Use Case that is now state of the art, how should we guarantee that the used technical approach is state of the art in e.g., 3 years? Especially in the field of AI, development and method evolution is unbelievable fast even for research – providing an AI based product needs much more time.

Wish:

- a list of journals/sources that represent the state of the art in that field.
- how to deal with method development / state of the art if one develops a model now compared to 3 years in future.

Regarding testing and reporting processes:

Are these required methods defined for the different AI-approaches in the medical field or are they the same for the different methods like:

- Supervised learning- and Classification tasks
- Unsupervised learning methods
- Reinforcement learning

Wish: It would be very helpful to define metrics/KPIs for every machine learning category like using confusion matrix with XYZ and the DICE score with GHJ etc.

No.	Chapter	Section	Article
REQ-01	*CHAPTER 3 REQUIREMENTS FOR HIGH-RISK AI SYSTEMS*	2	Art. 8 (1) High-risk AI systems shall comply with the requirements laid down in this Section, taking into account their intended purpose

			as well as the generally acknowledged state of the art on AI and AI-related technologies. Art. 8 (2) In ensuring the compliance of high-risk AI systems referred to in paragraph 1 with the requirements set out in this Section, and in order to ensure consistency, avoid duplication and minimise additional burdens, providers shall have a choice of integrating, as appropriate, the necessary testing and reporting processes.

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
ISS-01	*2 - Lack of definition*	*It is unclear, what the "state of the art" is.* *Also, the change of the "state of the art" during the development*	*Guidance Documents, harmonized standards.* *List of journals/sources that represent the state of the art in that field.*
ISS-02	*2 - Lack of definition*	*It is unclear if different methods are required for different AI-approaches.* - *Supervised learning- and Classification tasks* - *Unsupervised learning methods* - *Reinforcement learning*	*Guidance Documents, harmonized standards.* *Define metrics/KPIs for every machine learning category like using confusion matrix with XYZ and the DICE score with GHJ etc.*

Risk Management System Article 9

Regarding the AI-System, an identification and analysis of the known and the reasonably foreseeable risks that the high-risk AI system can pose to the health, safety, or fundamental rights when the high-risk AI system is used in accordance with its intended purpose needs to be done.

The risks need to be estimated and evaluated with its intended purpose and under conditions of reasonably foreseeable misuse.

Risks from a post-market monitoring system need to be considered and measurements need to be defined.

This is similar to the risk management process for medical devices.

Questions from our side

For our use case, the AI model acts as an expert system. The output of single steps or the output of the whole pipeline is ALWAYS reviewed by a technical specialist with expertise in the field of surgery planning AND the medical specialist in charge. From our technical point of view, such an AI system does never harm the health of the patient since patients never get an undiscussed treatment. Is the visual inspection and the agreement of involved specialists enough for health-related risks? Of course, the systems need to fulfill safety aspects as well as fundamental rights.

There are no probability thresholds determining if a AI system performs good enough. Are these values connected to state-of-the-art results based on scientific publications? Such values are usually produced under "laboratory conditions". Using a system in the real world probably performs worse. Minimum requirements would be helpful, e.g., DICE scores above 0.9

No.	**Chapter**	**Section**	**Article**
REQ-002	*CHAPTER 3 REQUIREMENTS FOR HIGH-RISK AI SYSTEMS*	2	Art. 9 (2) the identification and analysis of the known and the reasonably foreseeable risks that the high-risk AI system can pose to health, safety or fundamental rights when the high-risk AI system is used in accordance with its intended purpose; Art. 9 (6) High-risk AI systems shall be tested for the purpose of identifying the most appropriate and targeted risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and that they are in compliance with the requirements set out in this Section.

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
ISS-03	*2 - Lack of definition*	*It is unclear, how to evaluate the risks in case of an expert-system*	*Guidance Documents, harmonized standards.*

			List of journals/sources that represent the state of the art in that field.
ISS-04	*2 - Lack of definition*	*It is unclear how to evaluate the performance*	*Minimum requirements would be helpful, e.g., DICE scores above 0.9*

Data and Data Governance Article 10

Here, requirements for the data used to train, validate and test AI-models are given.

- The data collection processes and origin of data and, for personal data, the original purpose of data collection need to be described.
- The preparation of the data needs to be clear (e.g. for annotation, labelling, cleaning, updating, enrichment and aggregation)
- Regulation EU 2016/679 has to be fulfilled.

No further comments from our side.

Requirement 3 – Technical Documentation Article 11

This article states that we need to develop a technical documentation regarding Annex IV.

No further comments from our side.

Requirement 4 – Record-Keeping Article 12

This article gives requirements to records and that a logging-functionality need to be available.

No further comments from our side.

Requirement 5 – Transparency and Provision of Information to Deployers Article 13

This article summarizes the information within the instruction for use and that deployers shall be able to interpret a system's output and appropriate use.

Questions from our side

What means that the AI-model functioning is sufficiently transparent. Is the mathematical background sufficient to ensure transparency. In this case the AI-model is only "transparent" for mathematicians. Or is it necessary to implement tools, processes and methods established in the field of Explainable AI (XAI)?

Wish: standardized and reproducible methodology to ensure transparency in a sufficient way.

No.	**Chapter**	**Section**	**Article**
REQ-003	*CHAPTER 3 REQUIREMENTS FOR HIGH-RISK AI SYSTEMS*	2	Art. 13 (1) High-risk AI systems shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent to enable deployers to interpret a system's output and use it appropriately.

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
ISS-05	*2 - Lack of definition*	*It is unclear, what "sufficiently transparent" means.*	*Guidance Documents, harmonized standards.* *Clarification, if mathematical background is sufficient to ensure transparency*

Human Oversight Article 14

This article states that high-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use.

Additionally, the human oversight shall aim to prevent or minimize the risks to health, safety.

Questions from our side

That means it is sufficient that the AI output can be reviewed manually before the next steps are triggered which has the character of an expert system?

No.	**Chapter**	**Section**	**Article**
REQ-004	*CHAPTER 3 REQUIREMENTS FOR HIGH-RISK AI SYSTEMS*	2	Art. 14 (1) High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
ISS-06	*2 - Lack of definition*	*It is unclear, if* it is sufficient that the AI output can be reviewed manually before the next steps are triggered which has the character of an expert system	*Guidance Documents, harmonized standards*. *Clarification*

Accuracy, Robustness and Cybersecurity Article 15

As the article's title suggests, this article is about the robustness and resilience against unauthorized access.

No further comments from our side.

Application of EU AI act to potential use case ***Segmentation and classification of brain areas***

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Use Case:	**Segmentation and classification of brain areas (including cerebrospinal fluid) and their volume determination**[1]
Date:	**May 3rd, 2024**

Note: The use case "Segmentation and Classification of Brain areas (including cerebrospinal fluid) and their volume determination" is extracted from "Deutsche Normungsroadmap Künstliche Intelligenz | Ausgabe 2". The author of this paper was an active contributor to that edition of the "Normungsroadmap", hence, referencing this as further background information is available online within that edition.

[1] [1] DIN, DKE (2022): Deutsche Normungsroadmap Künstliche Intelligenz (Ausgabe 2); www.din.de/go/normungsroadmapki

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Use Case

Application example: **Segmentation and classification of brain areas (including cerebrospinal fluid) and their volume determination**

State of the art

Magnetic resonance imaging (MRI) has established itself as a standard procedure in neuroradiological diagnostics. In particular, it can be used to visualize various tissue structures as well as pathological changes in normal tissue. In addition to the visual evaluation of 3D MRI data, the diagnosis often requires a quantitative measurement of anatomical structures and, if necessary changes over time, e.g. to monitor the course of treatment. For conventional volume determination, selected anatomical structures must be segmented/imaged manually or semi-automatically (e.g. by contrast or edge detection). must be segmented / marked in the image.

However, this process is rarely carried out in everyday clinical practice due to time constraints. Alternatively simple length measurements are often used instead, which diagnostic significance is generally significantly limited compared to volume determination.

Specific Use Case

This use case describes an AI-supported, fully automated segmentation of all relevant brain areas.

For this purpose, the 3D MRI images of a patient's head are sent to a central image archiving and communication system (Picture Archiving and Communication System PACS for short) and analyzed there by a radiologist. The 3D MRI images are automatically analyzed, i.e. specific regions are volumetrically quantified and then visualized for radiologists (e.g. in a clear report that contains precise quantitative information and highlights specific lesions). The current case study is limited to an AI component, which supports the diagnosis of neurological diseases in in radiology. This AI component runs on a on a separate data processing computer unit that is locally
integrated into the radiology infrastructure. The calculations are performed by retrieving the data from the PACS. The output contents (reports and visualizations) are returned to the PACS after the calculation has been performed. These are made available to the radiologists together with the acquired 3D MRI images.
Users of the system can consequently use the results of the AI component as an additional source of information during the diagnosis and can thus supplement the purely qualitative diagnosis with quantitative information and additional visualizations. The established diagnostic is not replaced by the AI component but enriched by the additional information generated. Through the visualization of the AI-based results radiologists are able to assess the accuracy of the information generated by the AI

component. The comparison of the structures segmented by the AI with the anatomical reality present in the image data takes place within the framework of the professional competence of clinical users and does not require any specific training in relation to the AI component.

Executive Summary

Please consider the following passus in the *Deutsche Normungsroadmap Künstliche Intelligenz | Ausgabe 2:*

> "The EU's planned AI Act adds an additional level of complexity, which involves interactions with existing regulations and can therefore result in additional burdens with regard to the conformity assessment of AI-based medical devices. In order not to hinder innovation in this relevant area disproportionately, inconsistencies between the planned AI Act and the MDR (e.g. in the area of risk management, databases for post-market surveillance) should be eliminated and duplication of effort should be minimized. Accompanying the design of the planned AI Act, the corresponding standards should be prepared to ensure consistent and efficient implementation of the requirements."

We identified several issues in the text "Artificial Intelligence Act" (P9_TA(2024)0138) related mainly to Chapter III – High Risk AI systems which are mentioned in the tables below.

Detailed Analysis

Chapter I: General Provisions | No Comment

Chapter II: Prohibited Artificial Intelligence Practices | No Comment

Chapter III: High-Risk AI System

No.	Chapter	Section	Article
III/1	Chapter III	1	Article 6 (3) Exclusion from definition of High-risk AI system
III/2	Chapter III	2	Article 14 (1) High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use.
III/3	Chapter III	3	Article 17 Quality Management System
III/4	Chapter III	5	Article 43 (3): For high-risk AI systems covered by the Union harmonisation

			legislation listed in Section A of Annex I,,, the provider shall follow the relevant conformity assessment procedure as required under those legal acts. The requirements set out in Section 2 of this Chapter 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. For the purposes of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with requirements laid down in Article 31(4), (10) and (11) has been assessed in the context of the notification procedure under those legal acts.
III/5	Chapter III	5	Article 43 (4) High-risk AI systems that have already been subject to a conformity assessment procedure shall undergo a new conformity assessment procedure in the event of a substantial modification, regardless of whether the modified system is intended to be further distributed or continues to be used by the current deployer. For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been predetermined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not constitute a substantial modification.
III/6	Chapter III	5	Article 48(5) Where high-risk AI systems are subject to other Union law which also provides for the affixing of the CE marking, the CE marking shall indicate that the high-risk AI system also fulfil the requirements of that other law.

Application of EU AI act to potential use case ***Segmentation and classification of brain areas***

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
III/1	Exclusions from definition of High-risk AI System	Paragraph 3 lists different conditions that if one or more are met then the AI system does not qualifies as 'high-risk'. Interpretation is necessary for paragraph 3 (b) "the AI System is intended to improve the result of a previously completed human activity". In our Tumor Segmentation Use Case the manufacturer could argue that the results of the AI system do not replace the radiologist's diagnosis but rather enriches it with the additional information generated. Meaning that the human activity – diagnosis – can be previously completed by the user/human.	Guidance on interpretation of these exclusion clauses specifically in Medical Devices context. Proposal to dive deeper into the classification discussion of this use case and provide it as a practical example within the guidelines established in Article 6 (5) or eventually modify Article 6 (3) as a result of adopting a delegated act as described in Article 6 (6).
III/2	Wording "High-risk AI Systems shall be designed … in such a way … that they can be effectively overseen by natural persons during the period in which they are in use."	What is the interpretation of "the period in which they are in use"? In our use case, the images are analyzed ideally before the radiologist access the patient file, so the results of the AI system are available already when the radiologist wants to start reviewing the images. If the product is built such that the results can be reviewed, is this already fulfilling the passus "effectively overseen by natural persons during the period in which they are in use.?" Or is it meant that during the calculation the oversight must be guaranteed?	Guidance necessary to address this topic.
III/3	"Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. "	Medical Device Manufacturers already must implement a Quality Management System.	It would be beneficial if the Medical QMS is acknowledge without further/more effort. Harmonisation of ISO 13485.

III/4	Lack of accredited Notified Bodies will cause bottleneck.	After the experience with MDR and accreditation of Notified Bodies, it is of summon importance that Notified Bodies get accredited in both MDR and AI Act in time.	Strategy to enable fast accreditation of Notified Bodies.
III/5	Lack of explanation how the "substantial modification" relates the "predetermined changes during conformity assessment" and GenAI.	Some high-risk AI System may use e.g. Large Language Models with continue to learn after being placed on the market.	Examples are necessary how the predetermined changes document shall enclose most changes such that further learning does not constitute a substantial modification.
III/6	Guidance necessary to fulfill this requirement	The medical device described in the Use Case will need to draw up one Declaration of Conformity and affix the CE marking. Article 48(5) highlights that the "CE marking shall indicate that the high-risk AI system also fulfil the requirements of " the MDR. If the conformity assessment for MDR is performed by a different Notified Body than the conformity assessment for the AI Act, then two different identification numbers of the notified bodies shall be affix.	Guidance necessary on how two different identification numbers of notified bodies shall be affix.

Chapter IV: Transparency Obligations for Providers and Deployers of Certain AI Systems | No Comment

No comment

Chapter V: General Purpose AI Models | No Comment

No comment

Chapter VI: Measures in Support of Innovation | No Comment

No comment

Chapter VII: Governance | No Comment

No comment

Chapter VIII: EU Database for High-Risk AI Systems | No Comment

No comment

Chapter IX: Post-Market Monitoring, Information Sharing, Market Surveillance

No.	Chapter	Section	Article
IX/1	Chapter IX	1	Article 72(4) … providers shall have a choice of integrating, as appropriate, the necessary elements described in paragraphs 1, 2 and 3 using the template referred in paragraph 3 into systems and plans already existing under that legislation, provided that achieves an equivalent level of protection.

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
IX/1	"provided that achieves an equivalent level of protection"	This points to a justification as to why the post-market monitoring plan can be embedded into the Post Market Surveillance Plan of MDR. The question lies on whether the justification can be made at process level – within the QMS – or if it needs to be done on a product level.	In general guidance necessary on how to embed the AI Act into the manufacturer's QMS.

Chapter X: Codes of Conduct and Guidelines | No Comment

No comment

Chapter XI: Delegation of Power and Committee Procedure | No Comment

No comment

Chapter XII: Confidentiality and Penalties | No Comment

No comment

Chapter XIII: Final Provisions | No Comment

No comment

Annex IV: Technical Documentation referred to in Article 11 (1)

No.	Chapter	Section	Article
AIV/1	Annex IV		Paragraph 6: A description of ***relevant changes made by the provider*** to the system through its lifecycle;

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
AIV/1	Unspecific wording "relevant changes"	Failure to specify what "relevant changes" can cause extra burden on manufacturers/deployers.	Guidance document needed for the interpretation of this wording. In addition, reference to already existing guidance documents for significant/non-significant changes within MDR would be more advantageous.

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Use Case:	AI Rad Companion (Pulmonary)

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Use Case

AI-Rad Companion (Pulmonary):

Software solution intended to process, communicate, display, read, and archive medical data for informing and driving clinical management.

The software is intended to assist the physician in evaluating the lung.

The software provides the following functionality:

- Segmentation and measurements of complete lung and lung lobes.
- Identification of areas with lower Hounsfield values in comparison to a predefined threshold for complete lung and lung lobes.
- Dedication of found lung nodules to corresponding lung lobe.
- Detection of lung nodules (Lung CAD).
- Segmentation and measurements of solid and subsolid lung nodules.
- Correlation of segmented lung nodules of current scan with known priors and quantitative assessment of changes of the correlated data.
- Identification of areas with elevated Hounsfield values, where areas with elevated versus high opacities are distinguished.

Executive Summary

For medical devices, clarification of the qualification criteria as “high-risk AI systems” is urgently needed. Additional guidance and clarification is needed to avoid duplications when it comes to the essential requirements for high-risk AI systems. Overall, a clear understanding is needed of what needs to be addressed at the level of the “AI system” (which can generally be a component of a medical device) and what can reasonably be addressed at the level of the medical device (for example as part of existing processes and documentation).

Detailed Analysis

Chapter I: General Provisions

No.	Chapter	Section	Article
1	I	n.a.	Art. 2 (1) (c)

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Wording of clauses	Mismatch between definitions and intended scope: Art. 2 (1) (c) states that the Regulation applies to "providers and deployers of AI systems that have their place of establishment or are located in a third country, where the output produced by the AI system is used in the Union;". The intention seems to be that regardless of the location of provider or deployer, what matters is that the output is used in the Union. However, this intention is not supported by the underlying definitions, specifically for "provider", "placing on the market", and "putting into service": Providers are persons placing on the market or putting into service an AI system (or GPAI model), and "placing on the market" and "putting into service" are restricted to the Union. Thus, for AI systems, a provider only exists if the AI system is placed on the market or put into service in the Union, but not if the system is deployed outside of the Union. A system deployed outside of the Union whose output is used in the Union has no "provider".	Unknown

No.	Chapter	Section	Article
2	I	n.a.	Art. 3

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Wording of clauses	Definition and understanding of "safety component": The definition of "safety component" is not clearly understood for medical devices. It arguably comes from the machinery sector (although it is not aligned with the Machinery Regulation, either) where there are dedicated components for the (functional) safety of a product. For medical devices, a dedicated safety component is not generally used. For the described use case, it is not clear if the term "safety component" is applicable or not.	Provide guidance on the meaning of "safety component" for medical devices and IVDs. One approach could be: if this "component" fails or malfunctions, the device cannot effectively fulfil its intended purpose.
2	Conflict with MDR	Substantial modification" not aligned with MDR understanding of "significant change": For the MDR, the understanding of "significant change" is described in guidance document MDCG 2020-3 regarding changes to the design or the intended purpose. In the AI Act, Art. 3 (23) gives a definition of "substantial modification" that implies that changes to an AI system after its placing on the market that have been planned in the initial conformity assessment would not constitute substantial modifications. For medical devices that fall in the category of high-risk AI systems, certain modifications to the AI system would be permissible – if	In the development of guidance documents (per AI Act Art. 96), involve MDCG to provide guidance on the interplay of AI Act's understanding of substantial modification with the MDR understanding of significant change. It might also be appropriate to address this topic on the MDR side, therefore one solution would be that MDCG issues updated/new guidance on significant change, taking into account the interplay with the AI Act and its definition of substantial modification.

		they are planned at the time of the initial conformity assessment – without requiring a new conformity assessment, while the same changes arguably would require a new conformity assessment under the MDR. The conformity assessment procedure of MDR is understood to be the "leading" conformity assessment procedure in interplay with the AI Act, and it is not clear how changes to the AI system that would be "not substantial" under the AI Act could be made under the MDR conformity assessment. Example for use case: The algorithm for lung nodule detection of the described software solution is updated to improve the performance with regards to sensitivity. A change to an algorithm of the software solution is considered significant according to Chart C in guidance document MDCG 2020-3. If the algorithm change has been planned by the provider at the time of the initial conformity assessment, this change and resulting performance improvement would arguably not be a substantial modification under the AI Act.	
3	Conflict with MDR	In the AI Act, the definitions of "placing on the market", "putting into service" and "making available on the market" do not contain exceptions for investigational use. Under MDR, investigational devices are not considered as being placed on the market, put into service, or made available. This creates a situation where a high-risk AI system that is (part of) an investigational device would	Clarification is needed that, in case of investigational devices, the AI system is not considered to be placed on the market, put into service or made available according to the AI Act.

		need to be CE-marked under the AI Act, thus severely complicating clinical investigations if not making them altogether impossible for such devices. Example for use case: To investigate a possible broadening of the intended target population of the described use case to additional patient groups, a clinical investigation is planned for a new software version that is not a CE-marked medical device. The investigation results shall demonstrate whether the intended performance can be achieved for the additional patient groups or not. Data to further train and validate the AI model on which the AI system is based is processed with consent as part of the clinical investigation. Under the AI Act, however, the clinical investigation of the SaMD (incl. the AI system) can be understood as placing the AI system on the market, thus making it subject to CE-marking and conformity assessment requirements. The AI Act's requirements, for example, towards training and validation data cannot be met prior to starting the clinical investigation – the data has not been processed and it is yet unknown if the investigation results will show a satisfactory performance of the medical device for the new intended patient group. Thus, without CE-marking of the AI system, the clinical investigation of the medical device cannot be conducted.	

Chapter II: Prohibited Artificial Intelligence Practices

Chapter III: High-Risk AI System

No.	Chapter	Section	Article
1	III	1	Art. 6 (1)

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Wording of clauses	The qualification criteria given in Art. 6 (1) (a) are not sufficiently clear: - "the AI system is intended to be used as a safety component of a product": For medical devices, a dedicated safety component is not generally used. It is not clear in which cases this criterion is considered to be fulfilled. Is it meant specifically for AI systems that are part of a hardware product? See also the comment for the definition of "safety component". - "the AI system is itself a product": It is not clear in which cases the AI system is considered to be the product (in our case, the medical device), or only part of a (software) medical device. Example for use case: The described software solution is a "software as a medical device" (SaMD), containing AI-based algorithms as well as other, non-AI-based software components.	Develop guidance, involving MDCG, to provide clear interpretations of the qualification criteria in Art. 6 (1) (a) that are specific to medical devices (incl. IVDs). It needs to be unambiguously clear what is considered a "safety component" for medical devices, and when the criterion is fulfilled that the AI system is itself the medical device.

		Arguably, the SaMD does not have a safety component, because it is a standalone software product. This assumption is, however, subject to the interpretation of "safety component". Further, the AI system is a part of the SaMD, but is not equal to the SaMD, because the SaMD also contains other, non-AI-based software components. Further assumption: the intention behind the qualification criterion "AI system is itself a product" is that SaMD that contains an AI system fulfils this criterion.	

No.	**Chapter**	**Section**	**Article**
2	III	2	Art. 9

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Conflict with MDR	Risk management principles of AI Act and MDR: AI Act Art. 9 (10) clarifies that the aspects provided in Art. 9, paragraphs 1-9, can be part of or combined with existing risk management procedures established under Union Law, which includes MDR. Under MDR, risks need to be reduced as far as possible without adversely affecting the benefit-risk ratio, taking into account the clinical benefits of the medical device. According to AI Act Art. 9 (5) (a), it shall be ensured that risks are reduced as far as technically feasible.	The interpretation outlined in the column "Description of issue" should be supported by respective guidance. Overall, it should be clarified that risks, including risks associated with the AI system, are handled on the medical device level by the MDR-compliant risk management system, taking into account the clinical benefits of the device associated with its intended purpose.

		The AI Act does not have a concept of clinical benefits, but does state in Art. 9 (3) that the risks referred to in Art. 9 shall concern only those that can be reasonably mitigated or eliminated. In combination with the clarification in Art. 9 (10) (outlined in the first paragraph of this issue description), the provision in Art. 9 (3) seems to imply that, for medical devices, the intended purpose and the associated clinical benefits need to be considered because failure to do so could lead to "unreasonable" mitigation or elimination measures. Thus, when applying the AI Act's requirements towards a risk management system to a medical device, this needs to be done in accordance with the medical device's intended purpose (of which the AI system may only be a part).	

No.	**Chapter**	**Section**	**Article**
3	III	2	Art. 10

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Conflict with MDR and AI Act itself	Art. 10 (5) (e) states that "the special categories of personal data are deleted once the bias has been corrected". The technical documentation, according to MDR and the AI Act itself, needs to contain information that demonstrates conformity with the applicable (essential/general safety and performance) requirements. If special categories of data are processed to detect and correct	Guidance is needed on how to fulfil the requirements towards bias detection and reduction, and technical documentation, that are in line with Art. 10 (5) (e).

		bias, and the data are then deleted to meet the AI Act's requirement in Art. 10 (5) (e), it seems that the data used to detect and correct bias cannot be considered part of the technical documentation (of the AI system, of the medical device).	

No.	Chapter	Section	Article
4	III	2	Art. 13

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Wording of clauses	Art. 13 could be interpreted to mean that an AI system needs to be supplied with dedicated, separate instructions for use. It should be possible to combine the required information with the instructions for use for the medical device.	Provide clarification that the information required according to Art. 13 can be provided as part of the medical device's instructions for use. It should be sufficient to identify the medical device manufacturer, not additionally the AI system provider, on the instructions for use.

No.	Chapter	Section	Article
5	III	2	Art. 14

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Wording of clauses	For human oversight, it is crucial to take the medical device's intended purpose and specified user groups into account. Generally, for medical devices, the required level of human oversight, including particularly the possibility to interrupt through a "stop" button, needs to be decided at the level of the medical device.	Provide clarification that for medical devices the human oversight needs to be adjusted to the medical device's intended purpose and user groups.

No.	Chapter	Section	Article
6	III	3	Art. 22

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Wording of clauses	For AI systems that are (part of) a medical device, it should be possible to have one authorized representative for the medical device who covers also the obligations under the AI Act.	Provide clarification that for medical devices, the authorized representative can also cover the obligations under the AI Act and that no duplicative nomination of authorized representatives is needed.

No.	Chapter	Section	Article
7	III	5	Art. 47 and Annex V

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Conflict with principles of CE-marking and issuing an EU declaration of conformity	Art. 47 states that the provider of a high-risk AI system shall issue an EU declaration of conformity with the information set out in Annex V. The information in Annex V includes a statement that the AI system complies with GDPR. It is, however, not clear what it means for an AI system to comply with GDPR. GDPR itself does not provide rules for the compliance of products to GDPR.	Guidance needs to be provided on the meaning of AI system compliance with GDPR.

Chapter IV: Transparency Obligations for Providers and Deployers of Certain AI Systems and GPAI Models

Chapter V: General Purpose AI Models

Chapter VI: Measures in Support of Innovation

Chapter VII: Governance

Chapter VIII: EU Database for High-Risk AI Systems

Chapter IX: Post-Market Monitoring, Information Sharing, Market Surveillance

No.	Chapter	Section	Article
1	IX	1	Art. 72

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Conflict with MDR	For AI systems that are (part of) a medical device, according to Art. 72 (4), the template to-be-developed by the EU Commission shall be used for the post-market monitoring plan when integrating the needed elements into existing systems and plans. MDR prescribed the necessary elements for a post-market surveillance plan in MDR Annex III. Since the template according to AI Act Art. 72 (3) does not yet exist, it is unknown if it can be integrated with an MDR-compliant post-market surveillance plan.	It needs to be ensured that the template for the post-market monitoring plan according to AI Act Art. 72 (3) does not create conflict with the MDR requirements for a post-market surveillance plan, and that existing post-market surveillance plans do not become invalid due to this new AI Act template.

Chapter X: Codes of Conduct and Guidelines

Chapter XI: Delegation of Power and Committee Procedure

Chapter XII: Confidentiality and Penalties

Chapter XIII: Final Provisions

No.	Chapter	Section	Article
1	XIII	n.a.	Art. 111 (2)

Nature of Issue			
Issue No.	**Cause of issue**	**Description of issue**	**Solution / mitigation measure**
1	Mismatch in transition periods	Art. 111 (2) states that the AI Act applies to operators of high-risk AI systems, that have been placed on the market or put into service, 24 months from the date of entry into force, in case those systems are subject to significant changes in their designs. Art. 113 (c), however, gives a transition period of 36 months for "Annex I high-risk AI systems". This can be interpreted in such a way that "Annex I high-risk AI systems" that are already "in the field" and are subject to a significant change need to fulfil the AI Act's requirements 12 months earlier than AI systems that are newly placed on the market/put into service. Example: "Annex I high-risk AI system" is placed on the market in May 2024. A significant change to the design is made in July 2026. Supposing an entry into force date of June 2024, the AI system needs to comply with the AI Act in July 2026. In contrast, when placing on the market a new "Annex I high-risk AI system" in July 2026, Art. 6 (1)	Clarify that for "Annex I high-risk AI systems", only 36 months (not 24 months) after entry into force, a significant change to the design would lead to application of the AI Act requirements.

		and the corresponding obligations would not apply.	