SVDGV | Pappelallee 78/79 | 10437 Berlin

Bundesministerium für Wirtschaft und Klimaschutz

[redacted]
[redacted]
[redacted]Berlin

Per Mail vorab an buero-vib@bmwk.bund.de

Kopie geht an:
[redacted]

Anisa Idris
Vorstand SVDGV

Spitzenverband Digitale Gesundheitsversorgung

Pappelallee 78/79
D-10437 Berlin
[redacted]
anisa.idris@digitalversorgt.de

11 June 2024

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

[redacted]

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:

Vorsitzender: Dr. Paul Hadrossek
Schatzmeister: Markus C. Müller

Spitzenverband Digitale
Gesundheitsversorgung e.V.

Pappelallee 78/79 | 10437 Berlin

Telefon: +49 30 62 93 84 94
Fax: +49 30 62 93 84 96
E-mail: impressum@digitalversorgt.de

www.digitalversorgt.de

Vereinsregisternummer: VR 37693 B
Vereinsregister Berlin, Amtsgericht
Charlottenburg

Bankverbindung apoBank
IBAN: DE88 3006 0601 0007 3667 91
BIC: DAAEDEDDXXX

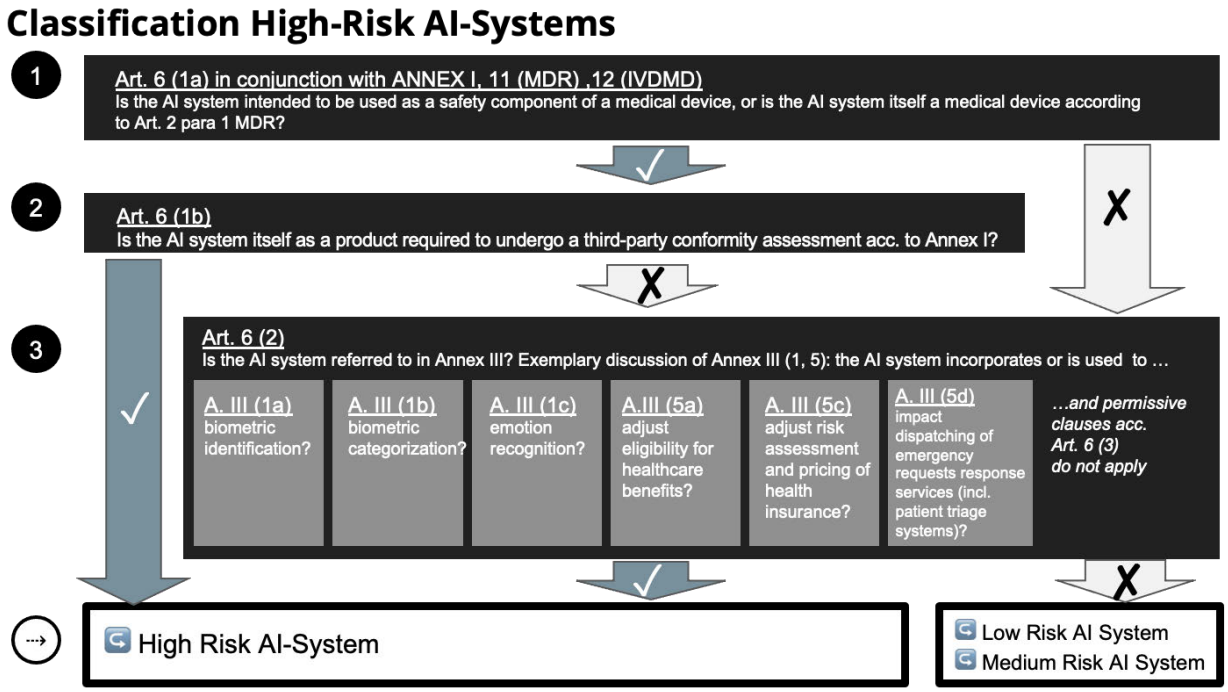

Chart 1: Schematic representation of the classification of High-Risk AI Systems acc. to EU AI Act

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:

Vorsitzender: Dr. Paul Hadrossek
Schatzmeister: Markus C. Müller

Spitzenverband Digitale Gesundheitsversorgung e.V.

Pappelallee 78/79 | 10437 Berlin

Telefon: +49 30 62 93 84 94
Fax: +49 30 62 93 84 96
E-mail: impressum@digitalversorgt.de

www.digitalversorgt.de

Vereinsregisternummer: VR 37693 B
Vereinsregister Berlin, Amtsgericht Charlottenburg

Bankverbindung apoBank
IBAN: DE88 3006 0601 0007 3667 91
BIC: DAAEDEDDXXX

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

Vorsitzender: Dr. Paul Hadrossek
Schatzmeister: Markus C. Müller

Spitzenverband Digitale
Gesundheitsversorgung e.V.

Pappelallee 78/79 | 10437 Berlin

Telefon: +49 30 62 93 84 94
Fax: +49 30 62 93 84 96
E-mail: impressum@digitalversorgt.de

www.digitalversorgt.de

Vereinsregisternummer: VR 37693 B
Vereinsregister Berlin, Amtsgericht Charlottenburg

Bankverbindung apoBank
IBAN: DE88 3006 0601 0007 3667 91
BIC: DAAEDEDDXXX

> ***"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.

Vorsitzender: Dr. Paul Hadrossek
Schatzmeister: Markus C. Müller

Spitzenverband Digitale
Gesundheitsversorgung e.V.

Pappelallee 78/79 | 10437 Berlin

Telefon: +49 30 62 93 84 94
Fax: +49 30 62 93 84 96
E-mail: impressum@digitalversorgt.de

www.digitalversorgt.de

Vereinsregisternummer: VR 37693 B
Vereinsregister Berlin, Amtsgericht
Charlottenburg

Bankverbindung apoBank
IBAN: DE88 3006 0601 0007 3667 91
BIC: DAAEDEDDXXX

Sincerely yours,

[redacted]

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)

Vorsitzender: Dr. Paul Hadrossek
Schatzmeister: Markus C. Müller

Spitzenverband Digitale
Gesundheitsversorgung e.V.

Pappelallee 78/79 | 10437 Berlin

Telefon: +49 30 62 93 84 94
Fax: +49 30 62 93 84 96
E-mail: impressum@digitalversorgt.de

www.digitalversorgt.de

Vereinsregisternummer: VR 37693 B
Vereinsregister Berlin, Amtsgericht
Charlottenburg

Bankverbindung apoBank
IBAN: DE88 3006 0601 0007 3667 91
BIC: DAAEDEDDXXX

Company / Industry Association:	Spitzenverband Digitale Gesundheitsversorgung (SVDGV) e.V. Pappelallee 78/79, 10437 Berlin Ada Health GmbH Neue Grünstraße 17, 10179 Berlin
Authors:	Anisa Idris Board Member SVDGV VP Market Access & Health Policy Ada Health
Contact Details:	[redacted] anisa.idris@ada.com
Use Case:	Ada Health App

Table of Contents

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