

# Policy paper ,Use of Artificial Intelligence in the context of assessment procedures by Notified Bodies‘

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## Preliminary remarks

- This policy paper was compiled by the German Notified Bodies Alliance (Interessengemeinschaft der Benannten Stellen für Medizinprodukte in Deutschland - IG-NB) and is intended to serve as orientation for Notified Bodies.
- The document makes no claim to completeness or mandatory application.
- Developing and implementing policies for the use of artificial intelligence (AI) in organizations is an important step in ensuring the ethical, safe and effective use of this technology. Although specific policies may vary from Notified Body to Notified Body, they are recommended to follow the framework given in this policy paper.
- The use of AI in conformity assessment procedures offers significant benefits, including efficiency gains, accuracy improvements and the ability to analyse large amounts of data. However, the design and implementation of such use requires policies to ensure that AI will be used ethically, transparently, fairly and in accordance with existing regulations and standards.
- The development and implementation of AI requires careful planning and consideration of ethical, legal and technical aspects to ensure the integrity of the process and maintain stakeholder confidence.
- AI tools can be used for different purposes within the framework of conformity assessment procedures (e.g. completeness check, translation, text generation, consistency and plausibility check, etc.).

General rules for the use of AI in conformity assessment procedures are (where applicable):

## 1. Transparency and traceability

- It must be clear and documented for which purposes an AI system may be used for.
- The use of AI systems for conformity assessment must be clearly documented. This requires relevant information for adequate control over of the algorithms, training data and the decision-making processes.
- The documentation of the results achieved by an AI system serves to ensure transparency, traceability and quality assurance in the context of conformity assessment. It also ensures that all regulatory requirements (e.g. MDR, IVDR) are met and serves to minimize risk when using AI-based decision-making processes. Therefore, all results of an AI system have to be documented when they form the basis for a decision.

## **2. Conformity with legal and regulatory requirements**

- AI systems must be in compliance with laws, regulations and standards, in particular with regard to data protection and security and especially for Europe the AI Act (Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence).
- The confidentiality requirements of Annex VII 1.3. Regulation (EU) 2017/745 and of Annex VII 1.3. Regulation (EU) 2017/746 have to be met.

## **3. Responsibility and liability**

- Notified Body are responsible when results of AI systems are used in conformity assessments.
- Conformity assessment decision are always made under full human oversight.

## **4. Competence and training**

- Persons using AI systems in conformity assessment procedures must be adequately trained to understand the capabilities and limitations of the systems.

## **5. Quality and reliability of the data, ethics and fairness**

- The quality of the data used to train an AI system is critical. Data must be accurate, up-to-date and representative to ensure the accuracy of AI decisions.
- It is necessary to have detailed information on the quality of the data.
- AI systems should be designed to respect ethical principles and avoid discrimination. This includes the implementation of mechanisms to detect and correct bias in algorithms.

## **6. Verifiability and validation**

- AI systems shall be validated for their intended purpose prior to being used in conformity assessment procedures.
- The performance of AI systems shall be verified in appropriate intervals and it shall be revalidated if necessary to ensure that they function correctly and continue to meet the specified requirements.

## **7. Continuous improvement**

- AI systems shall be updated and improved to increase their efficiency.
- AI systems shall be updated in a timely manner to follow changes in regulatory requirements.

## **8. Decommissioning**

- The decommissioning of an AI system has to be planned.
- All confidential data has to be permanently deleted.