<u>**ANNEX IV**</u>
<u>**TECHNICAL DOCUMENTATION referred to in Article 11(1)**</u>

The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system:

1.   A general description of the AI system including:

    (a)   its intended purpose, the person/s developing the system the date and the version of the system;

    (b)   how the AI system interacts or can be used to interact with hardware or software that is not part of the AI system itself, where applicable;

    (c)   the versions of relevant software or firmware and any requirement related to version update;

    (d)   the description of all forms in which the AI system is placed on the market or put into service;

    (e)   the description of hardware on which the AI system is intended to run;

    (f)   where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products;

    (g)   instructions of use for the user and, where applicable installation instructions;

2.   A detailed description of the elements of the AI system and of the process for its development, including:

    (a)   the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider;

    (b)   the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2;

    (c)   the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;

    (d)   where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);

    (e)   assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the users, in accordance with Articles 13(3)(d);

(f) where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Title III, Chapter 2;

(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness, cybersecurity and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f).

3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate;

4. A detailed description of the risk management system in accordance with Article 9;

5. A description of any change made to the system through its lifecycle;

6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of other relevant standards and technical specifications applied;

7. A copy of the EU declaration of conformity;

8. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 61, including the post-market monitoring plan referred to in Article 61(3).