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| **Company name and Address** | | |
| **Device Identification incl. version and Technical Documentation ID** (repeat in page headers)  [Title] | | **Basic UDI-DI** |
| **Description of the Device** | | |
| **Range of Devices (models) covered by checklist** | | |
| **Risk classification + rule number** | | |
| **MDR Code and/or EMDN Number** | | |
| **Checklist ID and Revision No** (repeat in page headers)  [Subject] | | |
| **Prepared by** | **Approved by** | **Date checklist approved** (repeat in page headers)**:**  [Publish Date] |

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|  | **Artificial Intelligence and Machine Learning Systems** |  |  |  |  |
| AI0.1 | What is the claim for the performance of the AI/ML system? Please itemize the claim so that each function can recognized.  Example: System is used by **healtcare personnel** as **decision support** to **pre-screen** **common flu** in **otherwise healthy adults** based **on five parameters** (body core temperature, running of nose, headache, muscle pain, free form text of symptoms) |  |  |  |  |
| AI0.2 | What is the number of training samples per claim item? How do you justify that the sample is representative and number of samples is adequate? |  |  |  |  |
| AI0.3 | Are the training samples in the form of free text/images or forced classifications? |  |  |  |  |
| AI0.4 | Are the training samples from a single source (possibly causing a bias) or from multiple sources? Please define the sources and distribution of samples. |  |  |  |  |
| EU Ethics guidelines for trustworthy AI | | | See <https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai> | | |
| AI/E.1 | **Human agency and oversight:**  AI systems should empower human beings, allowing them to make informed decisions and fostering their fundamental rights. At the same time, proper oversight mechanisms need to be ensured, which can be achieved through human-in-the-loop, human-on-the-loop, and human-in-command approaches   * What is the used human oversight mechanism? |  |  |  |  |
| AI/E.2 | **Technical Robustness and safety:**  AI systems need to be resilient and secure. They need to be safe, ensuring a fall back plan in case something goes wrong, as well as being accurate, reliable and reproducible. That is the only way to ensure that also unintentional harm can be minimized and prevented.   * What is the fall back plan applied? |  |  |  |  |
| AI/E.3 | **Privacy and data governance:**  Besides ensuring full respect for privacy and data protection, adequate data governance mechanisms must also be ensured, taking into account the quality and integrity of the data, and ensuring legitimised access to data.   * How GDPR requirements have been implemented? * How quality and integrity of the data has been ensured? * What kind of access control mechanisms have been applied to ensure legitimsed access? |  |  |  |  |
| AI/E.4 | **Transparency:**  The data, system and AI business models should be transparent. Traceability mechanisms can help achieving this. Moreover, AI systems and their decisions should be explained in a manner adapted to the stakeholder concerned. Humans need to be aware that they are interacting with an AI system, and must be informed of the system’s capabilities and limitations.   * How has traceability been implemented? * How do you make users aware of the capabilities and limitations? |  |  |  |  |
| AI/E.5 | **Diversity, non-discrimination and fairness:**  Unfair bias must be avoided, as it could could have multiple negative implications, from the marginalization of vulnerable groups, to the exacerbation of prejudice and discrimination. Fostering diversity, AI systems should be accessible to all, regardless of any disability, and involve relevant stakeholders throughout their entire life circle.   * How the unwanted bias has been addressed in training data? |  |  |  |  |
| AI/E.6 | **Societal and environmental well-being:**  AI systems should benefit all human beings, including future generations. It must hence be ensured that they are sustainable and environmentally friendly. Moreover, they should take into account the environment, including other living beings, and their social and societal impact should be carefully considered.   * What is the intended impact of the system to the society? |  |  |  |  |
| AI/E.7 | **Accountability:**  Mechanisms should be put in place to ensure responsibility and accountability for AI systems and their outcomes. Auditability, which enables the assessment of algorithms, data and design processes plays a key role therein, especially in critical applications. Moreover, adequate and accessible redress should be ensured.   * How have you addressed possible responsibility issues i.e. if the AI makes incorrect decisions and puts patients health in jeopardy, how and by whom it must be addressed? * Is it possible to trace back what has caused the incorrect decision? * Who will have the responsibility? |  |  |  |  |
| Johner Institute set of questions: | | | See <https://www.johner-institute.com/articles/software-iec-62304/artificial-intelligence/> | | |
| AI1 | How did you reach the assumption that your training data has no bias?  (Otherwise the results would be wrong or only correct under certain conditions.) |  |  |  |  |
| AI2 | How did you avoid overfitting your model?  (Otherwise, the algorithm would only correctly predict the data it was trained with.) |  |  |  |  |
| AI3 | What makes you assume that the results are not just randomly correct? (For example, it could be that an algorithm correctly decides that an image contains a house. But that the algorithm did not recognize a house, but the sky.) |  |  |  |  |
| AI4 | What requirements does the data have to meet in order to correctly classify your system or predict the results? Which framework conditions must be observed?  (Since the model was trained with a certain quantity of data, it can only make correct predictions for data coming from the same population.) |  |  |  |  |
| AI5 | Would you not have achieved a better result with another model or with other hyperparameters?  (Manufacturers must minimize risks as far as possible. These also include risks resulting from incorrect predictions made by sub-optimal models.) |  |  |  |  |
| AI6 | Why do you assume that you have used enough training data? (Collecting, processing and “labeling” training data is time-consuming. The more data that is used to train a model, the more powerful it can be.) |  |  |  |  |
| AI7 | What gold standard did you use when labeling the training data? Why do you consider the chosen standard to be the gold standard? (Particularly if the machine starts to be superior to people, it becomes difficult to determine whether a physician, a group of “normal” physicians, or the world's best experts in a discipline are the reference.) |  |  |  |  |
| AI8 | How can you ensure reproducibility if your system continues to learn?  (Continuous Learning Systems (CLS), in particular, must ensure that the further training does not, at the very least, reduce performance.) | N/A |  | Note: At the moment there is no basis to certify CLS in Europe. |  |
| AI9 | How have you validated systems that you are using to collect, prepare, and analyze data, and to train and validate your models?  (An essential part of the work consists of collecting and processing the training data and using it to train the model. The software needed for this is not part of the medical device. However, it is subject to the requirements of the Computerized Systems Validation. ) |  |  |  |  |

**Notes and instructions:**

1. The space on page 1 may be changed to suit your approval and issue requirement.
2. If the requirement is deemed N/A then a written justification must be included in the fifth column.
3. In the fourth column enter the reference number and version of any standard/ specifications that has been used as reference.
4. In the fifth column describe the documents, procedures or reports that are used as evidence of satisfying the requirement. Also indicate at which location the documents, procedures or reports are being kept if this useful.
5. Use of standards is preferred, but not compulsory. If other means are used, it should be expected that the notified body must use substantial additional time to verify and and validate the results with regard to compliance.

The text in blue font is intended as guidance and can be removed from the final checklist.