IG-NB
Interessengemeinschaft der Benannten Stellen für Medizinprodukte in Deutschland

Questionnaire „Artificial Intelligence (AI) in medical devices“

(Version 4, 09.06.2022)

Preliminary remarks:

- This questionnaire 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, manufacturers and interested third parties.
- This questionnaire is based in part on the „Guideline for AI for medical devices“ by Christian Johner, Christoph Molnar et al. (ai-guideline/Guideline-AI-Medical-Devices_EN.md at master · johner-institut/ai-guideline · GitHub).
- This questionnaire follows the idea that the safety of AI-based medical devices can only be achieved through a process-oriented approach, whereby all relevant processes and phases of the life cycle must be considered. Accordingly, the guideline does not place specific requirements on the products, but on the processes.
- The document makes no claim to completeness or mandatory application.
- The focus of the assessment results from the intended use.
- Questions regarding IT security of medical devices can be found in IG-NB's "Questionnaire IT security for Medical Devices".

References:

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (2017/745/EU)
- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (2017/746/EU)
- REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (2016/679/EU)
- COMMISSION IMPLEMENTING REGULATION (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices (2021/2226/EU)
- EN ISO 13485:2016-08 Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 14971:2013-04 Medical devices - Application of risk management to medical devices
- ISO/IEC 25010:2011-03 Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - System and software quality models
- IEC EN 62304:2016-10 Medical device software - Software life-cycle processes
- IEC EN 62366:2008-09 Medical devices - Application of usability engineering to medical devices
- IEC EN 82304-1:2018-04 Health Software – Part 1: General requirements for product safety
- MEDDEV 2.7/1 revision 4 (MEDDEV 2.7/1)

Main changes to Version 3:

- Translation German / English
- Reference to 2021/2226/EU instead of 207/2012/EU [B 5 b 15]
- Adjustments/corrections in: B 1 d 3; B 1 d 4; B 1 d 9

Table of contents:

A) General requirements

1. Certifiability of AI

Static AI (AI that has learned and operates in a learned state) is in principle certifiable.

Dynamic AI (AI that continues to learn in the field) is not certifiable in principle, as the system must be verified and validated (among other things, the functionality must be validated against the intended use).

For static „black box AI“ (AI that does not explain how it arrives at a result), regulatory requirements (including 2016/675/EU Articles 22 and 35 (General Data Protection Regulation), 2017/745/EU Annex I No. 17.2, 2017/746/EU Annex I No. 16.2, MDCG 2020-1) set limits on certification. The possibility of certification requires a review by the Notified Body and is a case-by-case decision.

2017/745/EU Annex II No. 4 or 2017/746/EU Annex II No. 4 applies.

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2. Processes

The manufacturers should cover all aspects listed below either in the procedural instructions or in the relevant plans to ensure that the safety of the product is systematically guaranteed. Normally, the following standard operating procedures or plans are affected:

- Development
- Risk management
- Data management
- Verification or validation (if not part of development)
- Post-market surveillance and vigilance
- Service, installation, decommissioning
- Customer communication
- Management review (ISO 13485:2016 requires consideration of “applicable new or revised regulatory requirements”.)

If the manufacturer outsources processes, the requirements apply accordingly. Examples would be a (software) development service provider or contract research organization to be required to consider the relevant chapters of this guideline.

3. Competences in development

1.	Has the manufacturer created a list of all roles that are directly or indirectly concerned with AI?	• ISO 13485, 6.2. • ISO 14971, 3.3.

		• IEC 62304
2.	Has the manufacturer identified AI-related skills for each role (e.g. developers, statisticians, modellers, etc.)?	• ISO 13485, 6.2. • ISO 82304, 6.1.
3.	Does the manufacturer has adequate records of education, training and competences to conclude that the persons actually have these competences?	• ISO 13485, 6.2.
4.	Does the (software) development plans lay out the product-specific competences (beyond or deviating)?	• ISO 13485, 7.3.2. • ISO 82304, 6.1.
5.	Is the integration of external competences done according to the rules on outsourced processes? How are outsourced competences recorded/documented?	• ISO 13485, 4.1.5., 7.3.2.

4. Documentation

1.	Has the manufacturer documented compliance with the requirements for AI as part of the general safety and performance requirements?	• 2017/745/EU, Annex I, 17.2., 17.4. • 2017/746/EU, Annex I, 16.2., 16.4. • ISO 13485, 7.3.6., 7.3.7.

B) Requirements for product development

1. Intended use and stakeholder requirements

a) Intended use

1.	Has the manufacturer determined for which medical purpose (diagnosis, therapy, monitoring, predictions) is to be used and for which parts of the intended use an AI is to be used?	• ISO 13485, 4.2.3., 7.3.2. c.
2.	Has the manufacturer characterized the patients to be diagnosed, treated or monitored with the medical device? Does this characterization includes indications, contraindications and associated diseases?	• 2017/745/EU, Annex II, 1.1. c • 2017/746/EU, Annex 2, 1.1. c • IEC 62366-1, 5.1., 5.3. • ISO 13485, 7.3.3 a.
3.	Has the manufacturer specified on which body locations the product will be used or from which body location the data originate?	• 2017/745/EU, Annex II, 1.1. • 2017/746/EU, Annex II, 1.1. • IEC 62366-1, 5.1.3.

b) Intended user, intended context of use

1.	Has the manufacturer characterized the intended users, e.g. - using demographic features (age, gender), - regarding the training and experience in medical domains, - regarding technical knowledge, - using physical and mental limitations, linguistic skills and cultural background?	• IEC 62366-1, 5.1.
2.	Has the manufacturer characterised the intended use environment (also with regard to the social environment, influenced by stress, shift work, frequently changing colleagues, etc.)?	• IEC 62366-1, 5.1., second to last paragraph

c) Stakeholder requirements

1.	Have the stakeholder requirements been identified by the manufacturer and translated accordingly into the performance specifications?

2.	Has the manufacturer defined all markets and all relevant regulatory requirements there (e.g. CMDE Guideline for Assessments for China)?

d) Input for risk management and clinical evaluation

1.	Has the manufacturer listed alternative methods to AI and evaluated them with regard to benefit, safety and performance?	• 2017/745/EU, Annex I, 1. • 2017/746/EU, Annex I, 1. • MEDDEV 2.7/1
2.	Has the manufacturer justified why AI is superior to conventional methods and thus justifies the associated risks?	• 2017/745/EU, Annex I, 1. • 2017/746/EU, Annex I, 1. • MEDDEV 2.7/1
3.	Has the manufacturer drawn up a list of risks specifically arising from the use of AI techniques?	• ISO 14971, 4.3., 4.4.
4.	Has the manufacturer analysed the risks that arise when users other than the specified users use the product?	• ISO 14971, 5.
5.	Has the manufacturer analysed the risks arising through use in an environment different than that specified?	• 2017/745/EU, Annex I, 14.2.(d) • 2017/746/EU, Annex I, 13.2.(d) • ISO 14971, 5. • IEC 82304, 4.1. (b)
6.	Has the manufacturer analysed the risks posed by inputs that do not meet the specified formats and/or have not been generated according to the specified prerequisites?	• ISO 14971, 5. • IEC 82304, 4.1. (c)
7.	Has the manufacturer analysed the risks that arise if the outputs do not meet the specified quality criteria?	• ISO 14971, 4.2., 4.3., 5. • IEC 82304, 4.1.
8.	Has the manufacturer assessed the risks if the system is used in a different patient population than specified?	• ISO 14971, 4.2., 4.3., 5. • IEC 82304, 4.1.
9.	Has the manufacturer derived the quantitative quality criteria based on the state of the art?	• 2017/745/EU, Annex I, 1., 17.2.

	Has the manufacturer defined operational limits (e.g. dose limits) within which the AI system may operate? Has the manufacturer defined how to ensure that these operational limits are not exceeded?	• 2017/746/EU, Annex I 1, 1., 16.2. • ISO 13485, 4.1. • MEDDEV 2.7/1
10.	Is the training data set representative of the actual patient population? Has the manufacturer assessed the consequences if the system provides socially unacceptable outputs (e.g. discriminatory)?	• IEC 62366-1, 5.1.
11.	Has the manufacturer assessed the risks if the system is not available?	• 2017/745/EU, Annex I, 17.4. • 2017/746/EU, Annex I, 16.4. • IEC 60601-1, 14.13.

2. Software requirements

a) Functionality and performance

1.	Has the manufacturer derived quantitative quality criteria or requirements for the software or/and the algorithm from the intended use in a comprehensible way?	• ISO 13485, 7.3.3.
2.	Has the manufacturer for example considered the following quantitative quality criteria or requirements: - for classification problems: accuracy (mean or balanced accuracy), positive predictive value (precision), specificity and sensitivity; - for regression problems: mean absolute error and mean square error?	• ISO 13485, 7.3.3., 7.3.4. • IEC 62304, 5.2.
3.	Has the manufacturer specified the expected value ranges of the outputs?	• ISO 13485, 7.3.3., 7.3.4. • IEC 62304, 5.2.
4.	Has the manufacturer specified the requirements regarding repeatability and reproducibility of requirements?	• 2017/745/EU, Annex I, 17.1. • 2017/746/EU, Annex I, 16.1. • ISO 13485, 7.3.3., 7.3.4
5.	Has the manufacturer specified how the system will behave if the inputs do not meet the specified requirements?	• ISO 25010 • IEC 62304, 5.2.
6.	What requirements must be met in order to be able to detect misconduct, e.g. by means of self-tests?	• ISO 13485, 7.3.3.

	If the manufacturer uses self-tests: Has he explained which of the specified quality criteria are checked with it and which risks are thereby controlled? Is it specified how the system behaves in the event of negative results?	
7.	Has the manufacturer specified how fast the system must generate the outputs?	• 2017/745/EU, Annex I, 17.1. • 2017/746/EU, Annex I, 16.1. • ISO 13485, 7.3.3.
8.	Has the manufacturer specified the availability of the medical device?	• ISO 25010 • IEC 62304, 5.2. • ISO 14971, 4.3. • ISO 13485, 7.3.3.

b) User interface

1.	Has the manufacturer specified what the user interface must display if the requirements are not met in order to operate the system safely (e.g. inputs not valid or not expected)?	• 2017/745/EU, Annex I, 5. • 2017/746/EU, Annex 1, 5. • IEC 62366-1, 5.2.
2.	Has the manufacturer determined whether a quality of output needs to be provided to the user? If so, how is the quality indicated to the user?	• 2017/745/EU, Annex I, 5. • 2017/746/EU, Annex 1, 5. • IEC 62366-1, 5.2., 5.3.
3.	Has the manufacturer determined whether an instructions for use and training materials are required?	• 2017/745/EU, Annex I, 23. • 2017/746/EU, Annex I, 20. • ISO 13485, 4.2.3.

c) Additional software requirements

1.	Is it documented in the product file which goal the machine learning procedures pursue?	• ISO 13485, 7.3.3.

2.	Has the manufacturer specified the data interfaces, including the formats and, in the case of images, their specific properties (size, resolution, colour coding)?	• IEC 62304, 5.2.2.
3.	Has the manufacturer determined the run-time environment of the product in terms of hardware (screen size, screen resolution, memory, network connection, etc.) and software (e.g. operating system, browser, run-time environments such as Java Run-time Environment or .NET)?	• 2017/745/EU, Annex I, 17.3., 17.4. • 2017/746/EU, Annex I, 16.3., 16.4. • IEC 62304, 5.2.2. • ISO 13485, 7.3.3.
4.	Has the manufacturer specified the input data requirements?	• 2017/745/EU, Annex I, 5. • 2017/746/EU, Annex I, 5. • IEC 62366-1, 5.2.

d) Risk management and clinical evaluation

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e) Security risks of artificial intelligence

Note: In addition to already known cybersecurity risks for software-assisted medical devices and software medical devices (see IG-NB's „Questionnaire IT Security for Medical Devices“), there are also AI-specific attacks. These are fundamentally different from conventional cyberattacks, which are mostly due to „bugs“ or human errors in the code. Cyberattacks against AI are usually directed against inherent vulnerabilities in the underlying algorithms, which cannot be fixed or can only be fixed with difficulty. So-called adversarial attacks aim to manipulate the decision/classification of the AI.

1.	Has the manufacturer identified the cybersecurity risks applicable to the AI, such as poisoning attacks, evasion attacks or model extraction etc.?	• ISO 13485:2016, 7.1 • 2017/745/EU, Annex I, 3 (b) • 2017/746/EU, Annex I, 3 (b)

2.	Has the manufacturer searched and documented sources (such as Adversarial ML Threat Matrix, MAUDE database and others) for identifying threats against AI models?	• ISO 13485:2016, 8.4 • ISO 14971:2019, 7.2
3.	Has the manufacturer considered and assessed the identified security risks in its risk management?	• ISO 13485:2016, 7.3.3 c. • 2017/745/EU, Annex I, 3 (c) • 2017/746/EU, Annex I, 3 (c)
4.	Has the manufacturer defined risk minimisation measures for the identified risks?	• ISO 14971:2019, 7.2 • 2017/745/EU, Annex I, 3 (c) • 2017/746/EU, Annex I, 3 (c)
5.	Does the AI lifecycle take into account an AI security lifecycle?	• 2017/745/EU, Annex I, 17.2 • 2017/746/EU, Annex I, 16.2 • IEC 62304:2006+A1:2015, 5.1.1. (e) • MDCG 2019-16
6.	Have measures been implemented and taken into account hardening the algorithms against adversarial attacks?	• ISO 14971:2019, 10.2 • 2017/745/EU, Annex I, 1., 4. • 2017/746/EU, Annex I, 1., 4.

3. Data management

Data can generally be divided into training, validation and test data, which can be subject to different requirements. Insofar as not further specified in this chapter, the term ‘data‘ includes all three types.

a) Collection of the training, validation and test data sets

1.	Has the manufacturer specified the number of records and given a justification as to why this is sufficient?	/
2.	Has the manufacturer characterised the inclusion and exclusion criteria of data using relevant attributes?	/
3.	Has the manufacturer specified technical inclusion and exclusion criteria for data?	/
4.	Has the manufacturer described the procedure to ensure that records that do not meet the inclusion criteria or are to be excluded are in fact excluded?	/
5.	Has the manufacturer described the collected data using descriptive statistics?	/
6.	Has the manufacturer justified where it collects test data and why it is representative of the target population? Where appropriate, has it compared these with data from the Federal Statistical Office, scientific publications and registries?	/
7.	Has the manufacturer listed and discussed factors that could cause a bias of the validation and test data?	/
8.	Has the manufacturer analysed what influences the type and location of data collection has on the data?	/
9.	Has the manufacturer established a procedure to anonymise or pseudonymise data before training and testing?	/
10.	Has the manufacturer investigated and ruled out the possibility of label leakage?	/

b) Labelling of data

1.	In the case of supervised learning, did the manufacturer derive the labels from the intended use for which the training data is understood and justify this choice?	/
2.	In the case of supervised learning, did the manufacturer specify a procedure for labelling if no labels were yet present in the data?	/
3.	Does this procedure specify quantitative/qualitative classification criteria for labelling? Has the manufacturer justified the choice of these criteria?	/
4.	Does this procedure specify the requirements for the number, training and competence of the persons responsible for labelling?	/

5.	Does this procedure specify how the competence of the persons responsible for labelling is checked?	/
6.	Does this procedure specify how the persons responsible for labelling are trained and how the success of this training is evaluated?	/
7.	Does this procedure specify how the correctness of the labels is systematically reviewed? Has the manufacturer documented the choice of this rationale?	/
8.	Does this procedure specify how it is monitored that the persons responsible for labelling are also permanently capable and willing to perform during labelling?	/

c) Procedure for (pre-)processing of data

1.	Has the manufacturer set a procedure describing the (pre-)processing of the data?	/
2.	Does this procedure describe the individual processing steps such as conversions, transformations, aggregations, normalisation, format conversions, calculation of features and conversion of numerical data into categories (augmentation)?	/
3.	Does the procedure describe how the correctness of the intermediate steps and the final results is checked? Are these checks carried out on a risk basis?	• ISO 13485, 4.1.6., 7.3.2., 7.5.6.
4.	Does this procedure specify how values with different measurement scales or units are recognised and processed (normalisation of data)?	/
5.	Does this procedure specify how values determined with different measurement methods are detected and processed?	/
6.	Does this procedure specify how values or metadata with the same names (such as in column headers) are detected and processed?	/
7.	Does this procedure specify how missing values, outliers and unusable data within data sets are detected and processed? Has the manufacturer justified this specification?	/

d) Documentation and version control

1.	Has the manufacturer documented all points from sections 3. a to 3. c in a comprehensible way?	/
2.	Has the manufacturer all software for data processing, including the libraries used in the process, documented and under version control?	• ISO 13485, 4.1.6., 4.2.4., 7.5.6.
3.	Does the manufacturer has the training, validation and test data set under version control?	• ISO 13485, 4.2.5.

4. Model development

a) Preparation

1.	Has the manufacturer justified the selection of the features considered during training?	• ISO 13485, 7.3.2., 7.3.3.
2.	Has the manufacturer described the interdependence of the features, especially in the case of tabular data?	• ISO 13485, 7.3.2., 7.3.3.
3.	Has the manufacturer documented and justified the ratio in which it divides the data into training, validation and test data?	/
4.	Has the manufacturer documented the stratification used to divide the data into training, validation and test data?	/
5.	How does the manufacturer ensure the consistency of training data (e.g. dispersion of a specific parameter due to accidental transfer to the general public)?	/
6.	Has the manufacturer documented how it ensures that test data has not been used in both training and validating the model?	/
7.	If the manufacturer recodes the data specifically for the model or specifically for the library: Has he described the procedure?	/

b) Training

1.	Has the manufacturer determined, documented and justified the quality metrics based on the intended use for which he wants to optimise the model?	/
2.	Has the manufacturer trained and compared several model types (including simpler and interpretable models), where appropriate?	/

c) Evaluation

1.	Has the manufacturer documented the quality metrics for the different models, e.g. for a binary classification, with the help of a confusion table?	/
2.	Has the manufacturer assessed and documented the quality metrics for the different models not only globally, but also separately for different features, if applicable?	/
3.	Has the manufacturer examined the data sets that predicted particularly well and those that predicted particularly poorly?	/
4.	Has the manufacturer examined the data sets for which the model decision is particularly safe and particularly unsafe?	/
5.	Did the manufacturer justify the final choice of model on the basis of the quality criteria and the intended use, and in particular explain when simpler and more interpretable models were not used?	/
6.	For tabular data in particular, has the manufacturer considered displaying, for individual data sets, the features that particularly drove the model to make the decision (Explainable AI)?	/

7.	For tabular data in particular, has the manufacturer considered evaluating how and to what extent individual features would have to change for the model to arrive at a different prediction?	/
8.	For tabular data in particular, has the manufacturer considered analysing / visualising the dependence (strength, direction) of the predictions on the feature values?	/
9.	Has the manufacturer considered synthesising data sets that particularly activate the model?	/

d) Documentation

1.	Does the manufacturer has the model and/or training code under version and configuration control?	• ISO 13485, 4.1.6., 4.2.4., 7.5.6.
2.	Can the manufacturer reproduce the test and validation results?	• ISO 13485, 7.3.6., 7.3.3.
3.	Does the manufacturer has the SOUP (libraries and frameworks) under version and configuration control?	• IEC 62304, 8.1.2.
4.	Has the manufacturer documented the architecture of the model and the model itself including its hyper parameters?	• ISO 13485, 4.2.3., 4.2.5.
5.	Has the manufacturer described when they have worked with a "pretrained model" and shown why this "pretraining" is suitable for the task?	/
6.	Has the manufacturer documented the quality of the models based on the quality metrics?	• ISO 13485, 4.2.3., 4.2.5.
7.	In particular, for tabular data, has the manufacturer documented within which limits (e.g. feature values) the model achieves the requirements for the quality metrics?	• ISO 13485, 4.2.3., 4.2.5.

5. Product Development

a) Software development

1.	Has the manufacturer carried out and documented all required activities?	• IEC 62304 • IEC 82304
2.	If the manufacturer has implemented the model in another language or for another runtime environment: Has he made a plan which of the activities he has to repeat?	• IEC 62304 • IEC 82304
3.	Does the manufacturer check the performance (response times, resource consumption) on the target hardware (e.g. browser, mobile device)?	• 2017/745/EU, Annex I, 17.1., 17.3. • 2017/746/EU, Annex I, 16.1., 16.3.

4.	Has the manufacturer described how to verify all SOUP or OTS components?	• IEC 62304

b) Accompanying materials

1.	Do the instructions for use identify the version of the product with sufficient precision?	
2.	Do the instructions for use describe the intended use of the product including the expected medical benefit?	
3.	Do the instructions for use identify the intended patient population on the basis of indications, contraindications and - where relevant - other parameters such as age, gender, concomitant diseases or availability of information?	
4.	Do the instructions for use explicitly state the patients / data / use cases for which the product may not be used?	
5.	Do the instructions for use document the requirements for the input data (including formats, resolutions, range of values, etc.)?	
6.	Do the instructions for use specify the intended primary and secondary users according to the intended use?	
7.	Do the instructions for use describe what other prerequisites the product assumes (e.g. runtime environment, usage environment)?	
8.	Do the instructions for use describe the residual risks?	
9.	If useful: Do the instructions for use specify the data with which the model was trained?	
10.	If useful: Do the instructions for use describe the model or the algorithms?	
11.	If useful: Do the instructions for use specify the quality criteria?	
12.	Does the instruction for use list the factors that can have a negative impact on the quality criteria?	
13.	Does the instruction for use describe how updates are made?	
14.	Does the instruction for use identify the manufacturer and the channels through which inquiries can be made?	
15.	Do the instruction for use name the URL where the latest versions of the instructions for use can be found?	• 2021/2226/EU

c) Usability validation

1.	As part of the usability validation, does the manufacturer assess whether the users understand the instructions for use?	• IEC 62366-1
2.	As part of the usability validation, does the manufacturer assess whether users blindly trust the product or check the results?	• IEC 62366-1
3.	As part of the usability validation, does the manufacturer assess whether the users correctly recognise and understand the results?	• IEC 62366-1, 5.7. – 5.9.

d) Clinical evaluation

1.	Does the manufacturer assess in the clinical evaluation whether the promised medical benefit is achieved with the given quality parameters?	• 2017/745/EU, Annex XIV and Annex XV

		• 2017/746/EU, Annex XIII and Annex XIV • MEDDEV 2.7/1
2.	As part of the clinical evaluation, does the manufacturer assess whether the promised medical benefit corresponds to the state of the art?	• 2017/745/EU, Annex XIV and Annex XV • 2017/746/EU, Annex XIII and Annex XIV • MEDDEV 2.7/1

6. Product release

(essential points, not an exhaustive list)

1.	Has the manufacturer documented the models and data used against the above criteria?
2.	In risk management, has the manufacturer assessed the risks as acceptable and documented that all of the activities specified in the risk management plan were performed?
3.	Have remaining risks been communicated to customers?
4.	Has the manufacturer prepared a post-market surveillance plan?

C) Requirements for the post development phases

1. Production, distribution, installation

1.	Has the manufacturer described how it is ensured that only exactly the intended artefacts (files) are delivered in exactly the intended version in the product or as a product?	• IEC 62304, 5.8.8.
2.	Has the manufacturer described how the people responsible for the installation will know which is the latest version and how mix-ups during installation can be avoided?	• ISO 13485, 7.8.3., 8.3. • IEC 62304, 5.8.4.
3.	Has the manufacturer described how it will be ensured during installation that the requirements specified in the accompanying materials (see above) are actually fulfilled?	• ISO 13485, 7.5.3.
4.	Has the manufacturer established procedures to ensure that it can communicate with the operators and users of its products in a timely manner?	• ISO 13485, 7.2.3., 8.3.3. • IEC 82304, 8.4.
5.	Has the manufacturer specified and communicated minimum requirements regarding hardware, IT network characteristics and IT security measures, including protection against unauthorised access?	• 2017/745/EU, Annex I, 17.4. • 2017/746/EU, Annex 1, 16.4.

2. Post-Market Surveillance

1.	Has the manufacturer prepared a Post-Market Surveillance (PMS) Plan?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII
2.	Has the manufacturer specified in this PMS plan the data he intends to collect and evaluate?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII
3.	Has the manufacturer specified in the PMS plan at which quality criteria and thresholds it considers action necessary, in particular a reassessment of the risk-benefit balance?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII
4.	When setting these thresholds, has the manufacturer analysed which feedback loops may influence the thresholds themselves?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII

5.	When setting these thresholds, has the manufacturer analysed which self-fulfilling prophecies may influence the thresholds themselves?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII
6.	Has the manufacturer described in the PMS plan how it collects and analyses what information on adverse medical effects?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII
7.	Has the manufacturer described in the PMS plan how and which information on (adverse) behavioural changes or (predictable) misuse is collected and how these information are assessed?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII
8.	Has the manufacturer described in the PMS plan how it collects and assesses information on additional "adverse effects"?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII
9.	Has the manufacturer described in the PMS plan how and which information is collected to assess whether the data in the field is consistent to the expected data or training data?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII
10.	Has the manufacturer described in the PMS plan how and how often it will collect information on whether the product is still state-of-the-art?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII
11.	Has the manufacturer described in the PMS plan how and how often it will collect information on whether the ground truth or gold standard is still current?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII
12.	Has the manufacturer described in the PMS plan how and how often it verifies that changes are compliant with the Algorithm Change Protocol (ACP) and within the SaMD Pre-Specifications (SPS)?	• 2017/745/EU, Chapter VII • 2017/746/EU, Chapter VII

D) Supplementary References

- MDCG 2020-1 - Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software
https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2020_1_guidance_clinic_eva_md_software_en.pdf

- MDCG 2019-16 - Guidance on Cybersecurity for medical devices
https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_cybersecurity_en.pdf

- MDCG 2019-11 - Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR
https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2019_11_guidance_qualification_classification_software_en.pdf

- U.S. Food and Drug Administration - Good Machine Learning Practice for Medical Device Development: Guiding Principles
https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles