RADIOLOGY MOSCOW
ENTERPRISE IMAGING

QUESTIONNAIRE ABOUT THE SOFTWARE BASED ON AI TECHNOLOGIES/COMPUTER VISION

Section	Metrics	Answer	Comments
Company name			
1. Solution	1.1. Solution name	Free response in the «Comments» field	
	1.2. Imaging modality	Free response in the «Comments» field	
	1.3. Anatomical area	Free response in the «Comments» field	
	1.4. Application area	☐ Oncology ☐ Pulmonology ☐ Cardiology ☐ Neurology ☐ Chronic diseases ☐ Medical emergencies	
	1.5. Age group	Free response in the «Comments» field	
2. Clinical application scenario	2.1. Type of medical care	☐ Planned ☐ Emergency	
	2.2. Level of medical care	☐ Primary ☐ Secondary ☐ Tertiary	
	2.3. Stage of medical care	☐ Prehospital ☐ Hospital ☐ Outpatient	
	2.4. Stage of the clinical workflow, at which the results are provided to the user	Notification: ☐ Before viewing the worklist ☐ In the worklist ☐ After a study is opened ☐ Upon request (second opinion) ☐ Audit of a completed report	
	2.5. Ways in which the results are provided	☐ Binary assessment of a pathology presence ☐ Score/categorical assessment of a pathology presence ☐ Free text description ☐ Study report template ☐ Recommendations for patient management ☐ Visualization of the findings on images ☐ Schematic view	
	2.6. Decisions taken by the users based on theobtained results	☐ No decisions ☐ Selection of further methods to analyze the study ☐ Referring to a specialist ☐ Additional examination with other diagnostics methods ☐ Additional examination with the same method after a certain time period	
	2.7. Practical goals	☐ Time reduction between the diagnostic study finish and the report completion ☐ Improvement of the quality of work (e.g., reduction of the clinically significant errors) ☐ Audit of radiologists performance	

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3. Risks	3.1. What class of medical software does the proposed AI service belong to? (Only one answer is possible) *Software classification scheme is given at the end of the questionnaire.*	☐ Class 1 ☐ Class 2a ☐ Class 2b ☐ Class 3	
4. User categories	4.1. Who can use the AI service?	☐ Specially trained healthcare professionals ☐ Patient supervised by specially trained healthcare professionals ☐ Patient without supervision of specially trained healthcare professionals	
5. Functional capabilities	5.1. Automated analysis of medical images (DICOM files)	☐ Yes ☐ No	
	5.2. Prioritization in the worklist according to the automatically revealed pathology	☐ Yes ☐ No	
	5.3. Automated preparation of a draft radiology report based on the results of the analysis	☐ Yes ☐ No	
	5.4. Preliminary comparative analysis of studies of a single patient at different time points (dynamic study).	☐ Yes ☐ No	
6. Certification	6.1. Approvals of FDA and/or CE certification (class II).	☐ Yes ☐ No ☐ In progress	
	6.2. Actual implementations of the currently working software in medical centers: – at least 2 independent institutions; – more than 6 months of operation; – at least 1000 successfully completed studies (confirmed by users) for each task (if the software solves several tasks). *Please, provide a list (including contact information) of hospitals/clinical centers where your product was used or is being used and copies of the contracts/agreements with these sites (without confidential details) and a detailed report on the implementation results.*	☐ Yes ☐ No ☐ In progress	
	6.3. Scientific articles (original research works) published in peer-reviewed journals indexed by Scopus and/or Web of Science and included in the first and second quartile according to the International Scientific Journal & Country Ranking; proven diagnostic accuracy AUC≥0.8 (classic ROC curve) and increase of the radiology workflow efficiency (based on the comparison of reporting speed with and without the software, including timing)	☐ Yes ☐ No ☐ In progress	
7. Evidence	7.1. Once the development was completed, the accuracy of algorithms was assessed on independent data, i.e. medical database for testing differed from the one used for training, development and validation. That is, clinical tests were performed on data unknown to the algorithms.	☐ Yes ☐ No	
	7.2. Diagnostic accuracy was tested on data that included Caucasoid and Mongoloid races (if the information is not available, on data of Russian citizens)	☐ Yes ☐ No	

	7.3. Periodic update of diagnostic accuracy information (please, specify the period in comments)	☐ Yes ☐ No	
	7.4. A list of criteria that you used to evaluate the achievement of the practical goal (item 2.7). *Please, send summaries or reference letters written by the product users as well as the documents confirming the achievement of the claimed practical goal(s).*	Free response in the «Comments» field	
8. Functionality	8.1. Availability of a built-in accuracy assessment tool	☐ Yes ☐ No ☐ N/A	
	8.2. Processing time of a single radiology study (specify in sec.) *Please, specify system requirements*	sec	
	8.3. The result of software operation is series of images (DICOM format), with: – the possibility to synchronize with the original images of the study; – information on each slice contains the software name, version, diagnostic accuracy, the verification date and the exact time of completed study; – possibility to provide additional series with the analysis results (e.g. summary tables with the revealed findings in dynamics and/or particular images of findings). *Please, provide a list and examples of output files that your service delivers in clinical practice as well as the workstation screenshots to demonstrate the result presentation format.*	☐ Yes ☐ No	
9. Contract	9.1. Regular system updates, including those for diagnostic accuracy information	☐ Yes ☐ No	
	9.2. Software updates included in the price	☐ Yes ☐ No	
	9.3. All medical data, related materials and software results are the property of the customer	☐ Yes ☐ No	
Completed by (full name and contact details)			
Other information (if applicable)			

SOFTWARE CLASSIFICATION SCHEME

WHEN IDENTIFYING THE SOFTWARE CLASS, PLEASE SPECIFY THE CATEGORIES APPLICABLE TO THE SERVICE

When classifying the software that is a medical device, only one class may be assigned to each software (Table 1):

- Class 1: Low-risk software
- Class 2a: Medium-low risk software
- Class 2b: Medium-high risk software
- Class 3: High-risk software

Table 1. Software classification scheme

Clinical situation category	Information value		
	I	II	III
A	3	2b	2a
B	2b	2a	1
C	2a	1	1

EXPLANATORY NOTES:

INFORMATION VALUE

I – Crucial information

Information that is (a) crucial to make an informed clinical decision when making a diagnosis and/or providing treatment to a patient, and (b) used to take immediate and timely action:

- ☐ – When treating, preventing, or alleviating disease manifestations through the use of medicines, medical devices, or other treatment methods;
- ☐ – To detect diseases (i.e., for diagnosis or screening).

II – Information that requires clarification

Information that requires clarification and/or more details due to its insufficiency to make an informed clinical (medical) decision:

- ☐ – Information on the safe and effective use of medicines and medical devices that is used in the treatment of diseases;
- ☐ – Information used to predict the risk of disease development, as well as supporting information used to identify the signs and symptoms of the disease or make a preliminary or final diagnosis;
- ☐ – Classification or identification of early symptoms of the disease.

III – Information intended to provide the long-term treatment

Information that (a) is intended to provide the long-term treatment, (b) does not require immediate action, and (c) is meant to inform about diseases:

- ☐ – Information on the options available to diagnose, treat, prevent, or alleviate disease manifestations;
- ☐ – Information obtained by the software by collecting relevant data (e.g., data on patient diseases, used medicines or medical devices, etc.).

CLINICAL SITUATION CATEGORIES

Category A

The clinical situation is classified into Category A if the software is intended for use:

- ☐ – In case of emergency medical care;
- ☐ – In severe, extremely severe, and terminal general condition of the patient;
- ☐ – When determining the need for major therapeutic or surgical intervention;
- ☐ – In the diagnosis or treatment of diseases that pose a high risk to public health and/or for high-risk patients (including for vulnerable population group).

In this situation, the software can only be used by specially trained healthcare professionals.

Category B

The clinical situation is classified into Category B if the software is intended for use:

- ☐ – In case of urgent medical care;
- ☐ – In moderate general condition of the patient;
- ☐ – If the disease or condition does not require major therapeutic intervention;
- ☐ – In the diagnosis or treatment of diseases that pose a moderate risk to public health.

The software can be used both by specially trained healthcare professionals and by patient or other individual supervised by specially trained healthcare professionals. If the software is used by patient or other individual without supervision of specially trained healthcare professionals, this clinical situation is classified into Category A.

Category C

The clinical situation is classified into Category C if the software is intended for use:

- ☐ – In case of routine medical care;
- ☐ – In satisfactory general condition of the patient;
- ☐ – If the disease requires minor therapeutic intervention (usually, non-invasive) or long-term medical supervision;
- ☐ – In the diagnosis or treatment of diseases that pose a low risk to public health.

The software can be used both by specially trained healthcare professionals and by patient or other individual without supervision of specially trained healthcare professionals.

N.B.: If more than one provision may apply to the software,
the software class is determined according **to the highest potential risk.**

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