Short Public Report

1. Name and version of the IT product:

   Robotic Ultrasound System, Version: V1

2. Manufacturer or vendor of the IT product:

   Company Name: LATVIA MGI Tech, SIA.

   Address:

   Lidostas Parks A ieeja

   Mārupe, Mārupes novads

   LV-2167

   Contact Person:

   Miao Jiye
   +86 135 10185891
   miaojiye@mgi-tech.com

3. Time frame of evaluation:

   September 2022 – November 2023

4. EuroPriSe Experts who evaluated the IT product:

Name of the Legal Expert:	Dr. Jan-Peter Ohrtmann (Lawyer)
Address of the Legal Expert:	PricewaterhouseCoopers Legal AG Georg-Glock-Strasse 22 40474 Duesseldorf

Name of the Technical Expert:	Andreas Bethke
Address of the Technical Expert:	B³ | Informationstechnologie Papenbergalle 34 25548 Kellinghusen

5. Certification Body:

Name: EuroPriSe Cert GmbH
Address: Joseph-Schumpeter-Allee 25
53227 Bonn
Germany
eMail: contact@euprivacyseal.com

6. Specification of Target of Evaluation (ToE):
ROBOTIC ULTRASOUND SYSTEM provides customers with a robotic system enabling remote ultrasound exams. It integrates a robotic arm, remote control and ultrasonic imaging technology, which is used for remote ultrasonic diagnosis, and is composed of two independently working endpoints: a Doctor-end diagnostic device and a Patient-end ultrasound device. ROBOTIC ULTRASOUND SYSTEM is a hard- and software combination and personal data is processed by both devices individually as well as in exchange between them.

ROBOTIC ULTRASOUND SYSTEM has two main interfaces:

- Ultrasound together with the robotic arm performing the scan as part of the patient-end system,
- Workstation with simulated probe tele controlling the ultrasound as part of the doctor-end system.

The interface of the patient-end is placed on the control-end of the patient-end and serves the interaction between doctor and patient. Both devices

communicate and share data with each other through their interfaces to the signalling server.

There is no direct interface to MGI for maintenance or software updates.

The ToE includes:

- The Hardware, containing the Patient-end ultrasound device and Doctor-end ultrasound keyboard (control panel). Doctor-end system: mechanical components, operation control system, and audio-video system and Patient-end system: mechanical components, operation execution system, ultrasound device, audio-video system
- The Software, containing Control Software (for Doctor-end and Patient-end) and Signalling Server Software (information forwarding server) (infrastructure)
- The ToE is set up via the Patient-end and Doctor-end's intercommunication with the Signalling Server Software (information forwarding server), which is without internet connection.

The ToE does not include components needing mandatory internet connection. The ToE does further not include the payment process since this process precedes the use of the product and is self-contained. Finally, the ToE does not comprise the maintenance process and any related data processing operations.

7. General description of the IT product:
ROBOTIC ULTRASOUND SYSTEM is a hard- and software combination and personal data is processed by both devices individually as well as in exchange between them. Both endpoints are connected through a server. This connection can either be set up through the internet enabling the users to execute exams while being in different regions or by establishing a local using the same local area network (LAN). For the subjection of the certification, ToE is not under

internet connection. Therefore, ROBOTIC ULTRASOUND SYSTEM can be classified as an IT-product.

8. Transnational issues:
   Data processed with the ROBOTIC ULTRASOUND SYSTEM is stored and processed in the product at the location of the customer. No personal data is transferred to third countries.

9. Tools used by the manufacturer of the IT product:

Qt	5.15.0
Visual Studio 2019	16.1.1
JIRA	7.3.6
redmine	4.1.5
TestLink	1.9.14

10. Edition of EuroPriSe Criteria used for the evaluation:

    EuroPriSe Criteria January 2017

    EuroPriSe Commentary May 2017

11. Evaluation methods:
    The following evaluation methods have been conducted by the experts:

    - Online demonstration and evaluation of the product and review of corresponding documentation (Application View)
    - Review of Documents (see below)

There was no possibility of a ROBOTIC ULTRASOUND SYSTM being delivered to the evaluators.

The following documents have been included in the evaluation:

- ToE Description (drafted for the certification project)
- ROBOTIC ULTRASOUND SYSTEM Briefing 20210928-DE
- H-020-000066-00 ROBOTIC ULTRASOUND SYSTEM Robotic Ultrasound System User Manual_EN_WH_20201209-12986
- Data protection guidance for customers
- ROBOTIC ULTRASOUND SYSTEM Network Security Description
- ROBOTIC ULTRASOUND SYSTEM Software Test Report
- Supplier Data Security Policy and Standards
- Master Sales Agreement
- MGI Sales Agreement (for selling equipment and reagents)
- ROBOTIC ULTRASOUND SYSTEM Privacy and Security Handbook
- Test Cases Collection
- Data Protection Policy
- ROBOTIC ULTRASOUND SYSTEM Software Design Specification Outline
- ROBOTIC ULTRASOUND SYSTEM Data Flow Diagram
- ROBOTIC ULTRASOUND SYSTEM Data Flow Narrative
- Software and hardware list of ROBOTIC ULTRASOUND SYSTEM
- ROBOTIC ULTRASOUND SYSTEM PIA Questionnaire
- ROBOTIC ULTRASOUND SYSTEM PIA Report
- Development Tools of ROBOTIC ULTRASOUND SYSTEM
- Screenshots of the product

Furthermore, the experts conducted various interviews additionally via phone and email.

Evaluation results:

Set 1: Overview on fundamental issues

Firstly, it is important to stress that the controller for the processing of personal data using ROBOTIC ULTRASOUND SYSTEM will be MGI's customer, not MGI as the manufacturer of the product. MGI will neither function as a processor of personal data within the ToE.

Moreover, by using the ROBOTIC ULTRASOUND SYSTEM, only a minimum set of personal data is processed. A key feature of the product is that collection of personal data is restricted to a minimum. User registration information and log user activities are collected in the product to allow users to use the product. However, it is possible to log in to the system without supplying personal data but only with company information.

All data is transmitted and stored encrypted. If there is encryption (transformation of data with the help of an algorithm and a key) of data, this can be seen as a special case of pseudonymisation, if the encrypted data is the pseudonym of the unencrypted data and the process of de-pseudonymisation is only possible by applying the algorithm with the help of the key. So, the data is pseudonymized in the meaning of the GDPR.

Finally, the ToE is set up via the Patient-end and Doctor-end's intercommunication with the Signalling Server Software (information forwarding server), which is without internet connection.

Set 2: Legitimacy of Data Processing

Since the user of the product (i. e. the customer of MGI) is the data controller he/she needs to decide and assess the legal basis and all corresponding requirements according to GDPR. We found that MGI strongly facilitates compliance with the information duties and further general data protection principles, such as, for example, transparency and data minimization, by providing relevant and informative guidance for the customers.

Data processed with the ROBOTIC ULTRASOUND SYSTEM is stored and processed in the product at the location of the customer. No personal data is transferred to third countries by processing personal data in the ROBOTIC ULTRASOUND SYSTEM.

Set 3: Technical-Organizational Measures: Accompanying Measures for Protection of the Data Subject

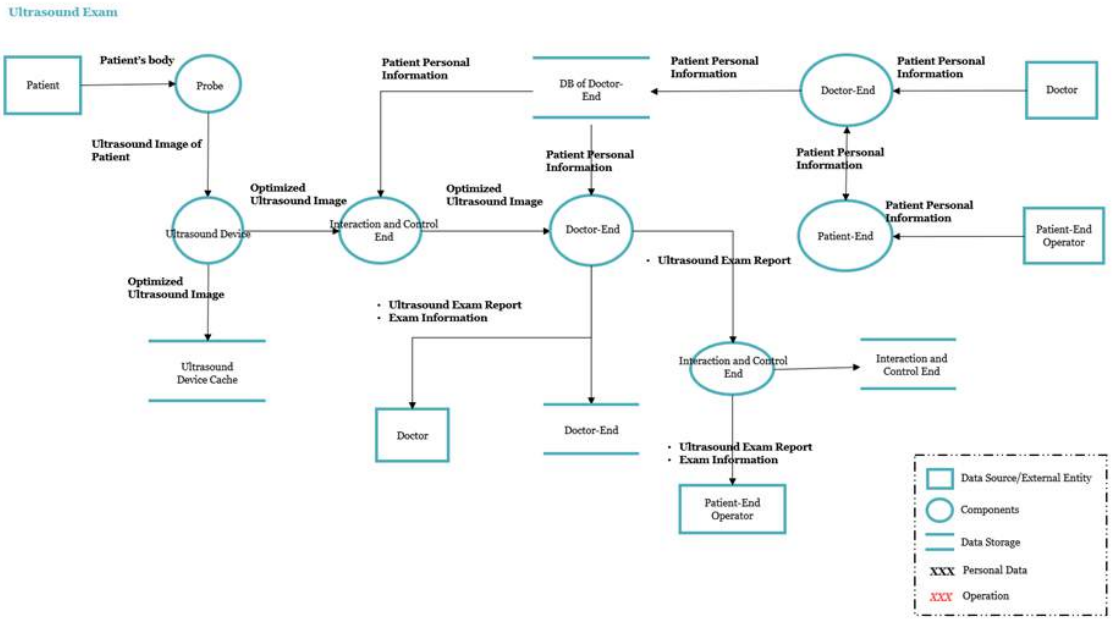
The ToE uses hardware and software that limits the processing of personal data to a necessary extent. The product has furthermore implemented access protection measures in several places. Mechanisms to prevent accidental loss of data; back-up mechanisms and recovery measures are adequately deployed. The principle of storage limitation is adequately observed. MGI as manufacturer supports the controller here by providing setting options for the storage period and an automatic deletion routine.

Set 4: Data Subjects’ Rights

MGI is not the controller in the case at hand. However, it provides the customer with a detailed guideline for responding to all relevant data subjects' rights. This also applies for information and guidance regarding the contents, manner, and method to fulfil the information duties pursuant to Articles 13 and 14 GDPR by the customer.

As a result, we consider the product to be designed in a way that adequately complies with all general data protection principles.

Data flow:



12. Privacy-enhancing functionalities:
    Especially by the clear and comprehensive guidance the manufacturer provides to its customers, a privacy compliant use of the product is facilitated.

13. Issues demanding special user attention:
    When customers process data of children, special attention to protective measures and safeguards should be paid. MGI offers guidance to handle these situations.

14. Compensation of weaknesses:
    Not applicable.

15. Decision table on relevant requirements:

EuroPriSe Requirement	*Decision*	*Remarks*
Data Avoidance and Minimisation	adequate	In ROBOTIC ULTRASOUND SYSTEM, MGI has embedded the

		principle of data minimization by way of limiting the data fields. For the customers and users of the product, a detailed guidance on how to observe this principle is provided by the “Data Protection Guidance” for customers” and the User’s Manual, where also precise suggestions and checklists are offered.
Transparency	excellent	There is extensive documentation on the product. MGI provides a very detailed “Privacy and Security Handbook” that describes in a transparent way the relevant data flows. Moreover, customers and users of the product will be provided with a “User’s Manual” and a “Data Protection Guidance” for customers. Thereby, customers are informed about their most important duties as controllers
Technical-Organisational Measures	adequate	The manufacturer fulfils all legal requirements for technical and organisational measures for data security.
Data Subjects’ Rights	adequate	When using the product the user can comply with the legal requirements regarding rights of data subjects. MGI provides its customers (controller) with a detailed and informative guidance on the particular data subject rights and, thereby, supports them in reacting appropriately to such rights.

Experts' Statement

We affirm that the above-named IT product has been evaluated according to the EuroPriSe Criteria, Rules and Principles and that the findings as described above are the result of this evaluation.

Duesseldorf, 04.12.2023 Dr. Jan-Peter Ohrtmann 

Place, Date	Name of Legal Expert	Signature of Legal Expert

Kellinghusen, 04.12.2023 Andreas Bethke 

Place, Date	Name of Technical Expert	Signature of Technical Expert

Certification Result

The above-named IT product passed the EuroPriSe evaluation.

It is certified that the above-named IT product facilitates the use of that product in a way compliant with European regulations on privacy and data protection.

Bonn, 08.12.2023 EuroPriSe Cert GmbH 

Place, Date	Name of Certification Authority	Signature