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MANUFACTURER INFORMATION	
Head Office Information	DATASURGERY YAZILIM VE DANIŞMANLIK ANONİM ŞİRKETİ AHMET YESEVİ MAH. KEREM SK. NO: 9 İÇ KAPI NO: 404 PENDİK/ İSTANBUL Contact person: Burcu Bektaş Güneş Contact person's email: burcu@traick.ai Tel: 0090505 2159814 Email: info@datasurgery.com.tr / info@traick.ai Website: https://www.datasurgery.com.tr/ SRN: TR-MF-000040270
Production	DATASURGERY YAZILIM VE DANIŞMANLIK ANONİM ŞİRKETİ AHMET YESEVİ MAH. KEREM SK. NO: 9 İÇ KAPI NO: 404 PENDİK/ İSTANBUL
Software	DATASURGERY YAZILIM VE DANIŞMANLIK ANONİM ŞİRKETİ AHMET YESEVİ MAH. KEREM SK. NO: 9 İÇ KAPI NO: 404 PENDİK/ İSTANBUL
Hardware	DATASURGERY YAZILIM VE DANIŞMANLIK ANONİM ŞİRKETİ AHMET YESEVİ MAH. KEREM SK. NO: 9 İÇ KAPI NO: 404 PENDİK/ İSTANBUL
Backup Adress	DATASURGERY YAZILIM VE DANIŞMANLIK ANONİM ŞİRKETİ AHMET YESEVİ MAH. KEREM SK. NO: 9 İÇ KAPI NO: 404 PENDİK/ İSTANBUL
INFORMATION ABOUT PRRC	
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PHONE OF THE PRRC	0090505 2159814
EU Authorized Representative	
Company Name	-
Address	-
Phone	-
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TRAICK Thyroid
Instructions for Use (IFU)

PREPARED BY	APPROVED BY
Name: Date: Signature:	Name: Date: Signature:

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1. REVISION HISTORY

No	Revision Date	Revision Reason
00	30.03.2026	First Issue
01		

PRODUCT NAME	Radiological Computer-Assisted Diagnostic Software for Thyroid Nodules/ TRAICK Thyroid
EMDN CODE (European Medical Device Nomenclature)	Z MEDICAL EQUIPMENT AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES Z11040192 ULTRASOUND SCANNERS - MEDICAL DEVICE SOFTWARE
UDI-DI CODE	2711980029TRAICKTHYROIDYM
MDR CODES	MDA 315-Software MDS 1009 Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable device MDS 1010-Devices with a measuring function MDT 2010-Devices manufactured using electronic components including communication device
BODY CONTACT	No
CONTACT POINT	N/A
CONTACT DURATION	N/A
INVASIVE	Non Invasive
SINGLE-USE	No
STERILE & STERILIZATION METHOD	N/A
SPECIFIC SUBSTANCE	No
ABSORBABLE	No
ACTIVE	Active device
	Software Version (Current Release) → v1.0.0 Software Lifecycle Standard Applied → IEC 62304 Class B Software Safety Class (IEC 62304) → Class B Cybersecurity Controls Implemented → IEC 81001-5-1 / MDCG 2019-16 AI / Machine Learning Used? → Yes Clinical Decision Support Type → CADx (Computer Assisted Diagnosis)
DOES IT INCORPORATE SOFTWARE?	Yes

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IS ANY SPESIFIC TECHNOLOGY USED?	No
CLASS	Class IIb
MDR CLASSIFICATION RULE	Rule 11
SHELF LIFE	-
IMPLANTATION INFORMATION	-

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ATTENTION

Read all instructions carefully before use. Follow all warnings and precautions specified in these instructions. Failure to do so may result in misinterpretation of clinical results or patient harm.

PRODUCT / TRADE NAME

Product Name: Radiological Computer-Assisted Diagnostic Software for Thyroid Nodules

Trade Name: TRAICK Thyroid

Software Version: v1.0.0

2. DESCRIPTION OF DEVICE

TRAICK Thyroid v1.0 is a standalone, active medical device software (Software as a Medical Device — SaMD) intended to assist qualified healthcare professionals in the detection, characterization, and risk stratification of thyroid nodules based on DICOM-formatted ultrasound images.

The software analyzes thyroid ultrasound images using artificial intelligence (deep learning) algorithms and provides:

- Automated detection and segmentation of suspected thyroid nodules
- Image-based analysis of nodule characteristics (composition, echogenicity, margin, shape, echogenic foci)
- Risk stratification according to the American College of Radiology Thyroid Imaging Reporting and Data System (ACR TI-RADS)
- A supplementary AI-derived indicator that maps the imaging-based assessment onto the malignancy ranges of the Bethesda System for Reporting Thyroid Cytopathology (TBSRTC, 2023 Edition), presented as a complement to the TI-RADS output and intended for decision-support purposes only; this indicator does not constitute a Bethesda category determination and does not require cytology data entry
- Structured reporting with malignancy probability scores
- Comparison of nodule progression across follow-up examinations

TRAICK Thyroid v1.0 is classified as a Computer-Aided Diagnosis (CADx) system because it not only detects nodules but also performs diagnostic classification and clinical risk assessment.

The device is intended to support clinical decision-making and does not replace physician judgment.

2.1 Software Architecture

TRAICK Thyroid v1.0 is deployed as a containerized web application using Docker on a Linux server (Ubuntu Server 22.04 LTS). It integrates with the hospital PACS (Picture Archiving and Communication System) via DICOM protocol for image acquisition.

2.2 Software Modules

Module	Function
Dashboard	Overview of cases, statistics, and system status
Diagnosis	Image upload (DICOM), AI-based nodule detection and classification, manual editing tools
Worklist	Patient case management, comparison of previous results, tracking

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Reporting	Structured report generation with ACR TI-RADS and Bethesda results, PDF export
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Delivery Method	Digitally distributed via secure, encrypted installation package
Input Data Format	DICOM ultrasound images
Output	Structured risk classification (ACR TI-RADS, Bethesda, malignancy probability, PDF reports)

3. SUBSTANCE INFORMATION

N/A — TRAICK Thyroid v1.0 is a software-only medical device. It does not contain or incorporate any medicinal substance, human blood or plasma derivatives, tissues of animal or human origin, CMR substances, endocrine disruptors, nanomaterials, phthalates, or natural rubber latex.

4. MECHANISM OF ACTION

TRAICK Thyroid v1.0 is a stand-alone active medical software device intended for use by qualified healthcare professionals to assist in the detection and risk stratification of thyroid nodules from ultrasound images. The software functions as a Computer-Assisted Diagnosis (CADx) system, integrating automated detection (CADE) with diagnostic classification and risk assessment based on internationally recognized standards, including ACR TI-RADS and, optionally, the Bethesda System for cytology data.

The device operates on DICOM-format ultrasound images and employs algorithm-driven image processing steps, including nodule detection, segmentation, feature extraction, and risk stratification. Using validated computational models and pattern recognition techniques, the software identifies suspected nodules, quantifies image-based features (e.g., echogenicity, margins, composition, shape, and presence of calcifications), and categorizes nodules into standardized risk classes to support clinical decision-making.

The software does not exert any pharmacological, immunological, metabolic, or physical action on the patient. Its effect is limited to processing, analyzing, and presenting imaging data to provide a structured risk assessment. The clinical benefit is achieved by enhancing diagnostic consistency, reducing inter-observer variability, and informing decisions such as the need for biopsy or follow-up, while maintaining that physician judgment remains central.

5. RISK CLASS AND RULE OF MEDICAL DEVICE

Classification: Class IIb

Applicable Rule: EU 2017/745 MDR, Annex VIII, Rule 11

Rule 11 applies because TRAICK Thyroid v1.0 is software intended to provide information used to make diagnostic decisions. The diagnostic output (ACR TI-RADS risk category, malignancy probability) may influence clinical management decisions regarding biopsy versus routine follow-up. Since incorrect classification could lead to a delayed diagnosis of thyroid malignancy, which may cause serious deterioration in health but not immediate death or irreversible deterioration, the device is classified as Class IIb.

6. ACCESSORIES AND COMPATIBLE DEVICES

TRAICK Thyroid v1.0 is a standalone software device. It does not have physical accessories. However, the following compatible systems are required for operation:



Compatible System	Description
Ultrasound Imaging Devices	Any ultrasound system capable of producing DICOM-format thyroid images
PACS	Picture Archiving and Communication System with DICOM connectivity
Server Hardware	Intel Xeon or AMD EPYC (8–12 cores, 2.5–3.5 GHz), 32–64 GB DDR4 ECC RAM, 1 TB NVMe SSD; GPU: NVIDIA GPU with CUDA support; NVIDIA Driver 595.x or higher; CUDA Toolkit 13.1+; cuDNN 9.12+; Python 3.12+; PyTorch 2.9+ (CUDA); ONNX Runtime (GPU build)
Operating System	Ubuntu Server 22.04 LTS or Ubuntu Desktop 22.04 LTS with Docker Engine (latest stable), Docker Compose (latest stable), NVIDIA Container Toolkit (required for GPU access); Kernel Version: 5.15+
Network	Dual 1 Gbps Ethernet for PACS connectivity
Display	Workstation monitor with minimum 1920×1080 resolution
Web Browser	Chrome, Firefox, Edge, or Safari (latest stable versions)

A deployment of TRAICK Thyroid v1.0 consists of:

- The software is delivered as a digitally signed installation package. Prior to installation, the digital signature and checksum must be verified to ensure package integrity.

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8. PURPOSE OF USE

TRAICK Thyroid v1.0 is intended to assist qualified healthcare professionals in the detection, characterization, and risk stratification of thyroid nodules based on DICOM ultrasound images, using AI-based analysis according to ACR TI-RADS. The software also generates a supplementary AI-derived indicator that maps the imaging-based assessment onto the malignancy ranges of the Bethesda System for Reporting Thyroid Cytopathology (TBSRTC, 2023 Edition). This Bethesda indicator is presented as a complement to the TI-RADS output, intended for decision-support purposes only, and does not constitute a Bethesda category determination.

9. INDICATIONS

- Detection, characterization, and risk stratification of thyroid nodules using DICOM-format ultrasound images
- Risk stratification of thyroid nodules according to ACR TI-RADS (TR1–TR5)
- AI-derived supplementary Bethesda risk correspondence indicator (TBSRTC, 2023 Edition) mapped from imaging-based assessment, particularly supporting evaluation of indeterminate nodules (Bethesda III/IV); this indicator is generated automatically from ultrasound image analysis and does not require cytology data entry
- Support for clinical decision-making regarding biopsy versus routine follow-up
- Longitudinal tracking and comparison of nodule progression across follow-up examinations

10. CONTRAINDICATIONS

TRAICK Thyroid v1.0 is not intended for use in the following situations:

- Patients without thyroid ultrasound imaging — the software requires DICOM-format ultrasound images to function
- Non-thyroid pathologies or anatomical regions — the device is validated only for thyroid nodule evaluation
- Use by untrained personnel or patients — accurate image acquisition, cytology data entry, and interpretation of AI-generated risk classifications require qualified healthcare professionals
- Non-compliant imaging formats or equipment — the software is validated for DICOM-format ultrasound images only
- Emergency or intraoperative settings without proper ultrasound imaging
- Images containing Doppler, elastography, or other overlays
- Images containing on-screen calipers, measurement markers, distance/size annotations, or other operator-applied measurement overlays within the region of interest
- Post-surgical excision sites or normal thyroid tissue without nodules
- Pediatric patients (< 22 years of age)
- Pregnant or breast-feeding women

11. ADVERSE REACTIONS AND COMPLICATIONS

TRAICK Thyroid v1.0 is a non-invasive, non-contact software device. It does not directly cause physical adverse reactions. However, the following software-related risks may indirectly affect patient outcomes:

- False-negative classification: The software may fail to identify a malignant nodule or may assign it a lower risk category than warranted. This could lead to a missed or delayed biopsy recommendation. The clinical consequence could be delayed diagnosis and treatment of thyroid malignancy.
- False-positive classification: The software may classify a benign nodule as high risk, potentially leading to an unnecessary biopsy or surgical intervention. The clinical consequence could be patient anxiety, procedural discomfort, and unnecessary cost.
- Image quality dependence: Poor-quality, incomplete, or improperly acquired ultrasound images may lead to inaccurate nodule detection or misclassification.
- Software malfunction: System errors, server failures, or network interruptions may result in loss of analysis results or inability to complete an assessment.
- Data security breach: Unauthorized access to patient data may result in privacy violations.

Mitigation: All diagnostic outputs must be reviewed and confirmed by a qualified healthcare professional. The software is a decision-support tool and does not replace clinical judgment. Refer to the Risk Management Report (DTSR-TD.01-10.02) for complete risk analysis.

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12. PATIENT PROFILE

TRAICK Thyroid v1.0 is used to analyze ultrasound images of patients with suspected or known thyroid nodules. The patient population includes:

- Adult patients (≥ 22 years of age) with suspected or known thyroid nodules. The software is not intended for use in pediatric patients (< 22 years), pregnant women, or breast-feeding women. Use in patients currently undergoing chemotherapy should be evaluated under the specific clinical discretion of a qualified physician.
- Patients undergoing thyroid nodule surveillance or follow-up
- Patients with indeterminate cytology results (Bethesda III/IV) requiring additional risk assessment

There are no patient-specific contraindications, as the software does not contact the patient.

13. USER PROFILE

TRAICK Thyroid v1.0 is intended for use exclusively by qualified healthcare professionals trained in thyroid ultrasound imaging and interpretation, including:

- Radiologists
- Endocrinologists
- Sonographers (under physician supervision)

The device is not intended for use by patients or untrained personnel.

14. DOSAGE

N/A — TRAICK Thyroid v1.0 is a software device used to analyze ultrasound images. There is no dosage. The software may be used for an unlimited number of analyses per patient and across patients, subject to license terms.

15. CONTACT POINT AND DURATION

N/A — TRAICK Thyroid v1.0 is a non-invasive software device that does not make physical contact with the patient. There is no body contact, contact point, or contact duration.

16. NAME OF DISEASE AND CLINICAL CONDITIONS

TRAICK Thyroid v1.0 is used in the clinical evaluation of:

- Thyroid nodules (benign and malignant)
- Thyroid carcinoma screening and risk stratification
- Indeterminate thyroid cytology (Bethesda III — AUS/FLUS, Bethesda IV — Follicular Neoplasm)
- Thyroid nodule surveillance and progression monitoring

Thyroid nodules are extremely common, found in up to 68% of adults on high-resolution ultrasound. The majority are benign, but approximately 5–15% may be malignant. ACR TI-RADS provides a standardized scoring system to stratify nodule risk and guide biopsy decisions. The Bethesda System provides standardized cytopathology reporting for fine-needle aspiration biopsy results. The integration of AI-based ACR TI-RADS and Bethesda assessment may reduce inter-observer variability and support more consistent clinical decision-making.

17. SHELF LIFE

TRAICK Thyroid v1.0 is a software medical device. The shelf life is defined as the period during which the software remains fully functional, secure, and supported by the manufacturer when operated according to specified system requirements.

The manufacturer shall provide security patches, bug fixes, and software updates during the supported lifecycle. The end-of-support date shall be communicated to users in advance.

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The software is validated and supported for five years from the date of release or installation, provided that regular manufacturer updates, patches, and maintenance are applied and the system meets minimum hardware and software requirements. Beyond this period, the manufacturer does not guarantee continued performance, security, or regulatory compliance. Refer to the manufacturer website (www.datasurgery.com.tr) for current support status and end-of-life notifications.

18. STERILIZATION INFORMATION

N/A — TRAICK Thyroid v1.0 is a software-only medical device. It is not sterile and does not require sterilization.

19. STORAGE CONDITIONS

TRAICK Thyroid v1.0 is a software-only medical device. No special physical storage conditions are required.

- Server-side storage:** The software application and associated data are hosted on secure servers maintained under controlled IT infrastructure conditions in accordance with applicable cybersecurity and data protection requirements.
- Local device storage:** When installed on local hardware, the system must meet the minimum hardware and software requirements specified in Section 6 of this document.
- Backup:** Regular backup of configuration data and patient analysis results is recommended in accordance with institutional IT policies.

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20. WARNINGS AND PRECAUTIONS

20.1 Clinical Use Limitation

- TRAICK Thyroid v1.0 is a non-invasive, diagnostic decision-support software.
- It does not replace clinical judgment and must not be used as the sole basis for diagnosis or treatment decisions.
- The assessment of nodule malignancy may differ from the physician's evaluation or final pathology results.
- Patient management decisions must always be made by a qualified healthcare professional, considering all clinical findings and other diagnostic information.

20.2 Qualified Users

- The software must be used only by trained healthcare professionals (e.g., radiologists or endocrinologists) experienced in thyroid ultrasound interpretation.

20.3 Image and Analysis Limitations

- The accuracy of the analysis depends on the quality, completeness, and proper acquisition of ultrasound images.
- Poor-quality or incomplete images may lead to inaccurate nodule assessment.

The software must not be used to evaluate:

- Normal thyroid tissue without suspected nodules
- Post-surgical excision sites
- Images containing Doppler, elastography, or other overlays

20.4 Device Compatibility

- Use only with ultrasound imaging devices capable of producing standard DICOM images.
- Ensure PACS connectivity is stable and properly configured.

20.5 Software Integrity

- Only manufacturer-provided updates, patches, or versions may be installed.
- Unauthorized modifications may compromise safety, cybersecurity, and device performance.
- Verify digital signature and checksum of the installation package before installation.

20.6 Data Security

- Users must ensure compliance with applicable patient data protection and privacy regulations (e.g., GDPR, KVKK).
- Unauthorized access may result in data breaches or loss of confidential patient information.
- Role-based access control must be maintained at all times.

20.7 Environmental and System Requirements

- The software must be operated within the manufacturer-specified hardware and software requirements.
- Operation outside recommended system specifications may cause malfunction or system errors.

20.8 Intended Use Restrictions

- The software is non-sterile and does not contact the patient.
- It must not be used for surgical procedures, biopsy guidance, implantation, or interventional purposes.
- It must not be used on portable handheld devices (e.g., smartphones or tablets). The software interface and all outputs are provided in English only; users must have adequate English proficiency to correctly interpret the software results.

20.9 Serious Incident Reporting

Notice to the user: Any serious incident that has occurred in relation to the device should be reported to the manufacturer (DATASURGERY YAZILIM VE DANISMANLIK A.S.) and the competent authority of the Member State in which the user and/or patient is established.

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21. DEVICE OPERATING INSTRUCTIONS

21.1 Installation

1. Verify that the server hardware meets the minimum system requirements specified in Section 6.
2. Verify the digital signature and checksum of the installation package.
3. Install Docker Engine and Docker Compose on Ubuntu Server 22.04 LTS.
4. Deploy the TRAICK Thyroid Docker image according to the installation guide.
5. Configure PACS connectivity (DICOM settings, AE Title, port).
6. Activate the software license using the provided activation files.
7. Verify successful installation by performing a test analysis with the provided validation dataset.

21.2 User Login

1. Open a supported web browser (Chrome, Firefox, Edge, or Safari).
2. Navigate to the TRAICK Thyroid server URL.
3. Enter authorized username and password.
4. The Dashboard module will be displayed upon successful authentication.

21.3 Image Upload and Analysis

1. Navigate to the Diagnosis module.
2. Upload thyroid ultrasound images in DICOM format from PACS or local storage.
3. Select the relevant patient and study.
4. Click the AI Diagnosis button to initiate automated analysis.
5. The software will automatically detect and segment thyroid nodules.
6. Review the detected nodules. Use manual editing tools (caliper markers) to adjust nodule boundaries if needed.

21.4 Results Review

1. Navigate to the Tools/Result screen.
2. Review the ACR TI-RADS parameter assessments (composition, echogenicity, margin, shape, echogenic foci).
3. Review the calculated ACR TI-RADS score and risk category (TR1–TR5).
4. Review the AI-derived Bethesda risk correspondence indicator and malignancy probability.
5. Manually modify any parameter if clinical judgment warrants adjustment; the system will recalculate scores accordingly.

21.5 Reporting

1. Navigate to the Reporting function.
2. Review the structured report including all nodule findings.
3. Add physician comments if needed.
4. Save and export the report as PDF.

21.6 Follow-Up Comparison

1. Navigate to the Worklist module.
2. Select the patient with previous examination results.
3. Use the Comparison function to review nodule progression between examinations.

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22. DEVICE PERFORMANCE CHARACTERISTICS

TRAICK Thyroid v1.0 meets the performance requirements established through the clinical evaluation process (DTSR-TD.01-20.01 Clinical Evaluation Plan, DTSR-TD.01-20.02 Clinical Evaluation Report).

Key performance characteristics include:

- Nodule detection sensitivity and specificity
- ACR TI-RADS classification accuracy for each parameter (composition, echogenicity, margin, shape, echogenic foci)
- Bethesda prediction accuracy
- Overall malignancy prediction performance
- Processing time per study

Detailed performance data are documented in the Clinical Evaluation Report (DTSR-TD.01-20.02).

23. USE INFORMATION AFTER APPLICATION

TRAICK Thyroid v1.0 is a software device. There is no physical disposal requirement. Upon end of support or decommissioning:

- Ensure all patient data are securely archived or deleted in accordance with institutional data retention policies and applicable data protection regulations.
- Revoke all user access credentials.
- Remove the software installation from the server.
- Notify the manufacturer of the decommissioning for post-market surveillance records.

24. INFORMATION OF SSCP

The Summary of Safety and Clinical Performance (SSCP) document, required under MDR Article 32, shall be made publicly available via EUDAMED upon CE marking. Access details will be communicated on the manufacturer website: www.datasurgery.com.tr

25. CYBERSECURITY INFORMATION

In accordance with IEC 81001-5-1:2021 and MDCG 2019-16, the following cybersecurity information is provided to ensure safe and secure operation of TRAICK Thyroid v1.0.

25.1 Cybersecurity Overview

TRAICK Thyroid v1.0 is a network-connected medical device software that processes patient health data (DICOM ultrasound images and associated metadata). The manufacturer has implemented cybersecurity controls throughout the software development lifecycle in accordance with IEC 81001-5-1:2021 (Health software and health IT systems safety, effectiveness and security) and MDCG 2019-16 Rev. 1 (Guidance on Cybersecurity for Medical Devices). The cybersecurity risk management process is integrated with the overall risk management per ISO 14971:2019. The manufacturer maintains a cybersecurity Bill of Materials (CBOM) documenting all third-party software components and their known vulnerabilities.

25.2 Security Architecture Summary

TRAICK Thyroid v1.0 employs a defense-in-depth security architecture consisting of: (a) Network layer security with TLS 1.2+ encryption for all data in transit between the client browser, application server, and PACS; (b) Application layer security with role-based access control (RBAC), input validation, and secure session management; (c) Data layer security with AES-256 encryption for patient data at rest, secure database access controls, and encrypted backup mechanisms; (d) Infrastructure layer security with Docker containerization providing process isolation, minimal attack surface through hardened Ubuntu Server 22.04 LTS base image, and firewall rules restricting network access to authorized ports and services only.

25.3 User Security Responsibilities

The operator/healthcare facility is responsible for: (a) Maintaining network infrastructure security including firewalls, intrusion detection systems, and network segmentation between the TRAICK Thyroid server and untrusted networks; (b) Managing user accounts by creating individual accounts for each authorized user, enforcing strong password policies (minimum 12 characters, complexity requirements), and promptly disabling accounts of users who no longer require access; (c) Ensuring physical security of the server hardware and preventing unauthorized physical access; (d) Maintaining up-to-date antivirus/anti-malware protection

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on workstations used to access TRAICK Thyroid; (e) Complying with applicable data protection regulations (GDPR, KVKK) including data processing agreements, data protection impact assessments, and patient consent procedures; (f) Reporting any suspected security incidents to the manufacturer within 72 hours at info@datasurgery.com.tr; (g) Maintaining backup procedures for system configuration and analysis data in accordance with institutional IT disaster recovery policies.

25.4 Secure Configuration Instructions

During initial deployment, the following secure configuration steps must be completed: (a) Change all default passwords immediately upon installation, including database and application administrator credentials; (b) Configure the server firewall to allow only required ports: HTTPS (443), DICOM (104 or configured port), and SSH (22, restricted to authorized IP addresses); (c) Disable all unnecessary operating system services; (d) Configure TLS certificates from a trusted Certificate Authority for HTTPS communication; (e) Set up DICOM communication security using TLS-secured DICOM associations where supported by the PACS; (f) Configure automated log rotation and centralized log forwarding to the institutional SIEM (Security Information and Event Management) system if available; (g) Enable automatic security updates for the underlying Ubuntu operating system; (h) Configure database access restrictions to prevent direct database access from external networks. Detailed secure configuration procedures are provided in the TRAICK Thyroid Installation and Configuration Guide.

25.5 Software Update and Patch Management

The manufacturer will release software updates including security patches, bug fixes, and feature enhancements. Users will be notified of available updates via email and through in-application notifications. Security patches addressing critical vulnerabilities will be issued as priority releases. All updates are digitally signed by the manufacturer; users must verify the digital signature before applying any update. Only manufacturer-authorized updates shall be installed. Unauthorized modifications, third-party plugins, or custom code injections are strictly prohibited and will void the product warranty and may compromise device safety and regulatory compliance. The update process is designed to preserve patient data and system configuration. A rollback mechanism is available in case an update introduces unexpected issues. The manufacturer recommends that operators apply security patches within 30 days of release for critical vulnerabilities and within 90 days for non-critical updates.

25.6 Vulnerability Disclosure Process

The manufacturer maintains a coordinated vulnerability disclosure process. Security vulnerabilities may be reported to info@datasurgery.com.tr with the subject line “Security Vulnerability Report — TRAICK Thyroid.” The manufacturer will acknowledge receipt within 5 business days, perform an initial assessment within 15 business days, and provide a remediation timeline based on severity classification (Critical: patch within 30 days; High: patch within 60 days; Medium: patch within 90 days; Low: addressed in the next scheduled release). Known vulnerabilities and associated mitigations are communicated to operators through security advisories distributed via email and published on the manufacturer website (www.datasurgery.com.tr/security). The manufacturer continuously monitors the Common Vulnerabilities and Exposures (CVE) database and third-party component advisories for newly discovered vulnerabilities affecting TRAICK Thyroid components.

25.7 Residual Cybersecurity Risks

Despite the implemented security controls, the following residual cybersecurity risks remain and require ongoing vigilance by the operator: (a) Zero-day vulnerabilities in third-party components (Docker, Ubuntu OS, web server, database) that have not yet been publicly disclosed or patched; (b) Advanced persistent threat (APT) attacks specifically targeting healthcare infrastructure; (c) Insider threats from authorized users with malicious intent; (d) Social engineering attacks (phishing) targeting user credentials; (e) Physical access to server hardware leading to data extraction or tampering; (f) Denial-of-service attacks that may temporarily prevent access to the application. These residual risks are managed through the manufacturer’s continuous monitoring process, timely patch releases, and the operator’s responsibility to maintain institutional security controls as described in Section 25.3.

25.8 Secure Decommissioning

When TRAICK Thyroid v1.0 is decommissioned, the following secure decommissioning procedures must be followed: (a) Export and securely archive all patient data in accordance with institutional data retention policies and applicable regulations (GDPR Article 17, KVKK); (b) Perform cryptographic erasure of all patient data on the server, including database records, DICOM images, analysis results, and log files; (c) Revoke all user accounts and access credentials; (d) Remove all Docker containers, images, and volumes associated with TRAICK Thyroid; (e) Remove the software license and activation files; (f) Securely wipe or physically destroy storage media if the server is being retired; (g) Notify the manufacturer at info@datasurgery.com.tr of the decommissioning for post-market surveillance records and license deactivation; (h) Retain decommissioning records documenting the data destruction process for audit purposes.

25.9 File Integrity and Cryptographic Controls

The manufacturer employs the following cryptographic controls to ensure software and data integrity: (a) All software installation packages and updates are digitally signed using asymmetric cryptography; the public key is available on the manufacturer website for independent verification; (b) SHA-256 checksums are provided for all distributed files; users must verify checksums before installation; (c) Patient data at rest is encrypted using AES-256 encryption; (d) All network communications use TLS 1.2 or higher

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with strong cipher suites; (e) User passwords are stored using bcrypt hashing with individual salts; plaintext passwords are never stored or transmitted; (f) API authentication tokens are time-limited and cryptographically signed (JWT with RS256); (g) Database backups are encrypted before storage; (h) The AI model files are cryptographically signed to prevent tampering with the diagnostic algorithms.

25.10 Logging and Monitoring

TRAICK Thyroid v1.0 generates comprehensive audit logs that record: (a) All user authentication events (successful logins, failed login attempts, logouts, password changes); (b) All patient data access events (image uploads, analysis requests, report generation, data exports); (c) All administrative actions (user account management, system configuration changes, software updates); (d) All security-relevant events (access denials, session timeouts, integrity check failures). Logs include timestamps (UTC), user identifiers, source IP addresses, and event descriptions. Logs are stored in a tamper-evident format and retained for a minimum period in accordance with institutional policy and applicable regulations. The operator is responsible for integrating TRAICK Thyroid logs with the institutional SIEM or log management system for centralized monitoring and alerting. The manufacturer recommends regular review of audit logs for anomalous activity patterns.

25.11 Session Timeout and Authentication

TRAICK Thyroid v1.0 implements the following authentication and session management controls: (a) Individual user accounts with unique credentials are required; shared accounts are not permitted; (b) Passwords must meet minimum complexity requirements (12+ characters, including uppercase, lowercase, numeric, and special characters); (c) Account lockout after 5 consecutive failed login attempts, with automatic unlock after 30 minutes or manual unlock by an administrator; (d) Automatic session timeout after 15 minutes of inactivity; the user must re-authenticate to resume; (e) Support for integration with institutional identity providers via LDAP/Active Directory where configured; (f) Role-based access control (RBAC) with defined roles (Administrator, Physician, Radiologist, Sonographer) limiting access to functions and data based on the user's role; (g) All authentication tokens are time-limited and invalidated upon logout.

25.12 User Guidance for Safe Operation

Users should follow these guidelines to maintain the security of TRAICK Thyroid v1.0: (a) Never share login credentials with other users; each user must have their own account; (b) Always log out when leaving the workstation unattended; (c) Do not access the software from untrusted or public networks; (d) Report any suspicious activity, unauthorized access attempts, or unexpected software behavior to the system administrator and the manufacturer immediately; (e) Do not install unauthorized software, browser extensions, or plugins on workstations used to access TRAICK Thyroid; (f) Do not attempt to access the database, Docker containers, or server filesystem directly unless authorized as a system administrator; (g) Ensure that DICOM images are transmitted over secure network segments; (h) Do not export patient data to unencrypted removable media; (i) Regularly review and update user account permissions to reflect current staffing.

25.13 Security Event Reporting

In the event of a suspected or confirmed cybersecurity incident involving TRAICK Thyroid v1.0, the operator must: (a) Immediately isolate the affected system from the network to prevent further compromise; (b) Document the incident including date, time, nature of the event, affected systems, and any observed anomalies; (c) Notify the manufacturer at info@datasurgery.com.tr with subject line "SECURITY INCIDENT — TRAICK Thyroid" within 72 hours; (d) Notify the institutional IT security team and the Data Protection Officer (DPO) as required by institutional policy and applicable regulations; (e) If the incident involves a personal data breach affecting patient data, notify the relevant supervisory authority (e.g., KVKK Board, national DPA) within the legally mandated timeframe; (f) Cooperate with the manufacturer's incident response team for investigation and remediation; (g) Do not attempt to modify, delete, or tamper with log files or evidence. The manufacturer maintains an incident response plan and will provide technical support for investigation, containment, and recovery.

25.14 Documentation and References

The cybersecurity controls described in this section are implemented in accordance with the following standards and guidance documents: IEC 81001-5-1:2021 (Health software and health IT systems safety, effectiveness and security), MDCG 2019-16 Rev. 1 (Guidance on Cybersecurity for Medical Devices), Regulation (EU) 2017/745 MDR Annex I GSPR 17.2 and 17.4, ISO 14971:2019 (Risk management for medical devices), IEC 62443 series (Industrial communication networks security, as applicable), OWASP Top 10 (Web application security risks). The manufacturer's internal cybersecurity documentation includes the Cybersecurity Risk Assessment, Software Bill of Materials (SBOM/CBOM), Threat Model, and Incident Response Plan, which are maintained as part of the technical documentation and are available for review by Notified Bodies and competent authorities upon request.

25.15 Supported and Maintained Software Definitions

Supported Software: A version of TRAICK Thyroid that is actively maintained by the manufacturer, receiving security patches, bug fixes, and technical support. The current supported version is v1.0.0. Maintained Software: Software components (operating system, Docker Engine, database, web server) that are required for TRAICK Thyroid operation and must be kept up to date by the

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operator. The manufacturer specifies supported versions of these components; operating with unsupported versions may compromise device security and is outside the manufacturer’s responsibility. End-of-Support: The date after which the manufacturer will no longer provide security patches or updates for a specific software version. The end-of-support date will be communicated at least 12 months in advance via email notification and the manufacturer website. After end-of-support, continued use of the software is at the operator’s own risk and the manufacturer cannot guarantee the safety or security of the device. End-of-Life: The date after which the software version is permanently retired. After end-of-life, the manufacturer recommends migration to a supported version or secure decommissioning as described in Section 25.8.

25.16 Summary Table

Data Encryption	Industry-standard encryption for data in transit (TLS) and at rest
Authentication	Role-based access control with secure user authentication
Software Integrity	Digital signature + checksum verification prior to installation
Update Policy	Only manufacturer-authorized updates. Unauthorized modifications compromise device safety and security.
Vulnerability Reporting	info@datasurgery.com.tr
End of Support	[To be defined — communicated to users in advance]

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26. SYMBOLS

The following symbols are used on the TRAICK Thyroid v1.0 label and packaging in accordance with ISO 15223-1:2021 and ISO 20417:2021.

Symbol	Meaning	Symbol	Meaning
	MANUFACTURER (ISO 15223-1, 5.1.1)		CATALOGUE NUMBER (ISO 15223-1, 5.1.6)
	DATE OF MANUFACTURE (ISO 15223-1, 5.1.3)		CONSULT INSTRUCTIONS FOR USE (ISO 15223-1, 5.4.3)
	SERIAL NUMBER (ISO 15223-1, 5.1.7)		MEDICAL DEVICE (ISO 15223-1, 5.7.7)
	CAUTION (ISO 15223-1, 5.4.4)	SW	SOFTWARE VERSION
	UNIQUE DEVICE IDENTIFIER (ISO 15223-1, 5.7.10)	2764	CONFORMITY EUROPEAN AND NOTIFIED BODY NUMBER