

Service Description: mytracekey UDI Manager

This service description describes the software in its current state and the service included in the subscription. During the term of your subscription, there may be changes or updates that affect the content of this description. The latest version can be found at <https://www.tracekey.com/en/general-terms-conditions/>. The contractual basis is always the latest version.

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1. Introduction

mytracekey UDI Manager is a cloud-based software solution that supports medical device companies in preparing, validating and reporting their product data to various databases in accordance with their requirements. The software is provided via a cloud in a software-as-a-service model.

mytracekey UDI Manager is available in the following packages: mytracekey UDI Manager FREE, FULL, EUROPE, PREMIUM, and ENTERPRISE. Multiple Add-On modules enable additional functionalities to these base packages. The packages differ in the scope of services and the functions that are included or can be added.

The included services of the mytracekey UDI Manager ENTERPRISE are described in the individual contracts and, therefore, are not part of this document.

2. Main Functions

This chapter describes the functional modules of the mytracekey UDI Manager. Each module is presented with its purpose and key features.

2.1. Productive System (Production)

- Purpose:
The Productive System is the customer's production tenant where live UDI product data is created, maintained, validated and prepared for regulatory reporting.
- Key Features:
 - Dedicated single-tenant instance in the production environment for the customer.
 - Full data entry, publication and versioning workflow for UDI product records.
- Operational Notes:
 - System updates are applied following the standard release cycle (first to sandbox, then to production).

2.2. Test System (Sandbox)

- Purpose:
The Test System (Sandbox) provides an isolated tenant for testing, training, validation and for safely evaluating changes and integrations without impacting live production data. Customers receive an individual tenant in the test environment.
- Key Features:
 - Separate sandbox tenant to test and validate system functionalities.
 - Release notes and change notes can be accessed and reviewed in sandbox before promotion to production.
- Operational Notes:

- Changes and new releases are deployed to sandbox first as part of the release cycle.

2.3. User Management

- Purpose:
Provide role-based access control and user lifecycle management to ensure appropriate and auditable access to the system.
- Key Features:
 - Create and invite users via email.
 - Predefined roles (Admin, UDI Data Manager) are available to restrict which apps and functions individual users may access.
 - User profile management with personal settings such as password change and system language.
- Operational Note:
 - The Admin role handles user administration and company master data.
 - The number of users per tenant is unlimited.

2.4. Validation Documents

- Purpose:
Supply the documentation and artifacts required for validation, installation qualification, operational qualification and audits.
- Key Features:
 - Validation deliverables such as Functional Specifications, User Requirement Specifications, Test Collections, Traceability Matrix, Installation Qualification (IQ) and Operational Qualification (OQ).
 - Release Notes and Change Notes that accompany software updates.
- Operational Notes:
 - Documentation available via the Docs app and the Self Service Portal for eligible subscriptions.

2.5. Audit Trail

- Purpose:
Maintain an auditable, time-stamped record of user actions and system events to support traceability and regulatory audits.
- Key Features:
 - Logging of user activity, data changes, publications and reporting events with timestamps and user identifiers.
 - Permanent, reviewable entries that show who performed which actions and when.

- Operational Notes:
 - Accessible through the Audit Trail application.

2.6. EUDAMED Compliance Module

- Purpose:

Assist customers in preparing and managing UDI product master data according to the formal criteria of EUDAMED.
- Key Features:
 - Preconfigured product templates for EUDAMED Basic UDI-DI, UDI-DI and Legacy Devices aligned with MDR, MDD, IVDR, IVDD and AIMDD to guide correct data entry.
 - Product entry can be done either manually or via Excel Import. Excel template to manage EUDAMED product data is provided for download.
 - EUDAMED Business Rules validation applied during manual entry, during Excel import and before publication.
 - XML export in EUDAMED bulk upload format for manual upload to EUDAMED.
- Operational Notes:
 - The system provides clear error messages and guidance if data does not meet EUDAMED Business Rules.
 - Reporting to EUDAMED can be performed via manual XML upload.

2.7. EUDAMED M2M Connection (Machine-to-Machine)

- Purpose:

Offer a secure, automated interface to EUDAMED for sending reports directly from the mytracekey system, removing the need for manual file transfers. Automated interface is done by Machine-to-Machine (M2M) connection to EUDAMED.
- Key Features:
 - Secure machine-to-machine (M2M) interface to transmit EUDAMED-formatted reports directly to customer's account in EUDAMED.
 - Transmission status tracking and persistent visibility of transmissions for audit and compliance evidence.
- Operational Notes:
 - The M2M Connection is provided as an add-on and requires activation and configuration.
 - Transmission logs and status are available in the Reports application of the system.

2.8. swissdamed Compliance Module

- **Purpose:**
Provide the rules, templates and reporting support necessary to comply with swissdamed UDI registration and requirements.
- **Key Features:**
 - Preconfigured product templates for swissdamed Basic UDI-DI, UDI-DI and Legacy Devices aligned with MDR, MDD, IVDR, IVDD and AIMDD to guide correct data entry.
 - Product entry can be done either manually or via Excel Import. Excel template to manage swissdamed product data is provided for download.
 - swissdamed Business Rules validation applied during manual entry, during Excel import and before publication.
 - Transformation of EUDAMED data to swissdamed data can be performed.
 - Secure machine-to-machine (M2M) interface to transmit swissdamed-formatted reports directly to customer's or representative's account in swissdamed.
 - Transmission status tracking and persistent visibility of transmissions for audit and compliance evidence.
- **Operational Notes:**
 - The system provides clear error messages and guidance if data does not meet swissdamed Business Rules.
 - Reporting to swissdamed can be performed via secure M2M interface.

2.9. AusUDID Compliance Module

- **Purpose:**
Support Australian UDI (AusUDID) requirements with dedicated templates, validation checks and reporting outputs suited to Australian regulatory processes.
- **Key Features:**
 - Product templates for UDI-DI and validation tailored to the fields and rules required by AusUDID.
 - Product entry can be done either manually or via Excel Import. Excel template to manage AusUDID product data is provided for download.
 - Secure machine-to-machine (M2M) interface to transmit AusUDID-formatted reports directly to customer's account in AusUDID.
 - Transmission status tracking and persistent visibility of transmissions for audit and compliance evidence.
- **Operational Notes:**

- The system provides clear error messages and guidance if data does not meet AusUDID Business Rules.
- The M2M Connection requires configuration. Transmission logs and status are available in the Reports application of the system.

2.10. Self Service Support (Help App)

- Purpose:
Providing a centralized repository of knowledge, training and onboarding materials for independent system operation of the user.
- Key Features:
 - User guides, FAQs, onboarding instructions, and training documents for common workflows and tasks in the software.
- Operational Notes:
 - The Self Service Portal is the primary resource for onboarding and daily use.

3. System Provisioning

The mytracekey UDI Manager is operated by us as a Software-as-a-Service solution in the Microsoft Azure Cloud and hosted in the European Union. The software is accessible via the browser, so that no requirements are placed on the customer's infrastructure.

Each customer receives their own tenant in the mytracekey system, which is only accessible to them and, if applicable, our support team. The mytracekey system is a multi-tenant system with operation in the Community Cloud. A tenant is made available to the customer with the booking. This customer tenant is created by tracekey after the order process has been completed. It enables our customers to access and use all functions of the booked version.

By booking the mytracekey UDI Manager, a user account is automatically created with the payment service provider (Stripe). This is the prerequisite for subscription management by the customer and cost accounting for the provision of the system.

4. Security

At tracekey, information security is a fundamental aspect of our business, especially as a SaaS provider for regulated industries. We take a risk-based approach to security that continuously monitors and addresses potential threats. Our Information Security Management System (ISMS) is based on ISO 27001 standards and focuses on practical, effective security measures. We use multi-factor authentication and industry-standard encryption to protect data, and our secure software development procedures include regular code reviews and penetration testing. Our infrastructure, hosted in Microsoft Azure data centers, ensures high availability and GDPR compliance.

We attach great importance to a high level of operational resilience through robust incident response and management, regular backups and redundancy systems. Our security culture is reinforced through continuous employee training and open communication on security issues. tracekey's managers are committed to maintaining high security standards, with clearly defined roles and responsibilities and strict supplier management practices. Our security processes are continually refined through regular reviews, audits and training so that we can respond to new threats and maintain a strong security posture. Furthermore, we have a quality management system and are regularly audited according to GxP and GAMP5, which contributes to the early identification and decisive prevention of potential security gaps.

Data protection is a high priority at tracekey. We work in accordance with the BDSG and the GDPR. This includes an internal data protection policy and regular training for our employees. In addition, we have appointed an external data protection officer, carry out regular internal audits, have appropriate contracts with our service providers and take technical and organizational measures to protect personal data. Further details can be found in the privacy policy on our website.

5. Support and Maintenance

The mytracekey UDI Manager is designed as a self-service tool. Onboarding and familiarization are carried out by the customer using the training material provided by tracekey. Technical support, for example in the event of system errors, is included in mytracekey UDI Manager FULL, EUROPE and PREMIUM. Our support team can be reached via email (help@tracekey.com).

Possible system updates are integrated in a four-week release cycle. The system updates are included in all subscription versions. The changes are first applied to the test environment (sandbox) and then transferred to the production system in the following release (after four weeks). The respective Release Note can be viewed via the tenant using the Docs App. Under certain circumstances, so-called hot fixes may occur in deviation from the release cycle.

mytracekey UDI Manager customers are not entitled to individual changes to the software.

6. Delimitation of Responsibilities

The customer is responsible for the content of the data and the uploading as well as other related tasks. tracekey checks for the formal requirement criteria of the respective authority (e.g. EUDAMED, swissdamed, AusUID) in accordance with the applicable Business Rules. The customer is responsible for the correctness of the data content.

The mytracekey UDI Manager solution is part of the overall mytracekey solution. The mytracekey solution has a service availability as stated in the following table:

Service Availability – (SAV)	
Required Level of Performance	97%
Calculation	IT Service Availability = $(A+B)/C \times 100$ A = Actual Uptime in minutes B = Permissible Downtime in minutes C = Scheduled Service Time The scheduled service time is calculated by the number of days in the month multiplied by 1,440 minutes per day. The Actual Uptime and permissible downtime are measured in minutes.
Measurement Point	Measurement of the roundtrip time between monitoring server and application server will be made available to CUSTOMER within the providing datacenter. Timeouts are counted as not available.
Measurement Method	Monitoring tools operated by tracekey with the results provided to CUSTOMER on request.
Measurement Period	Calendar month

7. Training and Validation Documentation

In all subscription versions the customer is provided with training documents and FAQs. These serve to enable the customer to use all functions of the mytracekey UDI Manager independently and effectively.

In addition, a comprehensive validation package is provided as part of the UDI Manager packages (except FREE). It consists of

- Self Service Portal
- Release Note
- Change Note
- Functional Specifications
- User Requirement Specifications
- Test Collection
- Traceability Matrix

- Installation Qualification (IQ)
- Operational Qualification (OQ)

The above-mentioned documents will be revised as required as part of the respective release and made available to the user.

8. Package Scope and Prices

The annual prices of the subscription packages consist of a base fee and a usage-based price component. The amount of the annual base fee is determined by the specific subscription booked and the associated scope of services.

The usage-based price component is based on the number of UDIs managed in the customer tenant. The UDIs are counted monthly by the system per customer client. All subscription versions already include an inclusive number of UDIs. As soon as the number of UDIs managed in the system exceeds the number of UDIs included in the subscription, these additional UDIs are charged monthly in accordance with the prices below. This billing is done monthly. If the initially booked inclusive number of UDIs is not reached, no credit will be issued.

Below are the current prices and included features per each subscription package:

	FREE	FULL	EUROPE	PREMIUM
Prices				
Annual base fee	0 €	1.188 €	1.908 €	2.148 €
UDIs included	10	100	100	300
€ per additional UDI/month	N/A	0,04 €	0,04 €	0,04 €
SRN included (per Compliance Module)	1	1	1	3
Functions				
Productive System (Production)	✗	✓	✓	✓
Test System (Sandbox)	✓	✓	✓	✓
User Management	✓	✓	✓	✓
Validation Documents	✗	✓	✓	✓
Audit Trail	✗	✓	✓	✓
EUDAMED Compliance Module	✓	✓	✓	✓
EUDAMED M2M Connection	✗	600 €/year	✓	✓
swissdamed Compliance Module	✗	300 €/year	✓	600 €/year
AusUDID Compliance Module	✗	960 €/year	960 €/year	1.440 €/year
Support				
Self Service Support (Help App)	✓	✓	✓	✓
Chatbot (In-App Assistance)	✗	✓	✓	✓
Support via Email	✗	✓	✓	✓

All prices quoted here do not include VAT. The applicable VAT will be displayed and charged separately during the purchasing process.

9. Methods of Payment

For the completion of a subscription via the tracekey webshop, we offer you the following payment options:

1. Debit and credit cards

The payment is made automatically each month by debiting your debit or credit card. We accept all major credit cards such as Visa, MasterCard and American Express.

2. SEPA direct debit

We collect the invoice amount of your order monthly from your bank account on file after the order has been placed.

The stored payment method can be edited via the customer portal.

10. Termination of Subscription

To terminate your mytracekey UDI Manager subscription, please send an email to our sales team at sales@tracekey.com, stating your company name and the email address linked to your contract. Termination requires one (1) month's notice to the end of the respective subscription term, in accordance with Clause 9 of the General Terms and Conditions. You will receive a written confirmation once your termination has been processed.