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.

Content

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 EUDAMED for the EUDAMED UDI/Device Registration Module in accordance with the MDR requirements. The software is provided via a cloud in a software-as-a-service model.

mytracekey UDI Manager is available in the following versions: mytracekey UDI Manager FREE, BASIC FULL, PREMIUM, and ENTERPRISE. A direct interface to EUDAMED can also be added (M2M). The versions 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, not described in this document.

2. Main Functions

The scope of the basic functions included differs according to the various subscription versions.

2.1. Functions of "mytracekey UDI Manager FREE"

The customer receives a single tenant in our multi-tenant system. mytracekey UDI Manager FREE includes access to one tenant in the test environment (SBX).

Each tenant in the UDI Manager FREE version contains the following apps and associated functions:

- **User Profile**
  The user can edit their own user profile and the user settings. Here, for example, the password can be changed or the system language set.
- **Start**
  Home page of the mytracekey UDI Manager software.

- **People**
  The main user (admin) can invite any number of additional users to the software via the People app. This is done via the e-mail address of the persons to be invited. In addition, preset roles can be assigned to each user. The assigned roles determine which functions (apps) are accessible to the respective user (role concept). Admin and UDI Data Manager are available as roles. Additional, application-based authorizations can also be set for each user.
  The following preset roles are available for UDI Manager BASIC:

UDI Data Manager

Apps

- Start
- Products
- Help

Tasks

- Configure and manage products
- Manage product hierarchy
- Import products
- Report products

Admin

Apps

- Start
- People
- Company Setup
- Help

Tasks

- User Administration
- Administration of Company Master Data

- **Company Setup**

  In this app, the mandatory company data for EUDAMED can be stored. Additionally, one authority can be configured.

- **Products**

  In this app, the UDI product data can be managed. For this purpose, product templates for the following regulations are stored in mytracekey UDI Manager: MDR, MDD, IVDR, IVDD, AIMDD. The UDI product data can be entered manually into the software or imported collectively in an Excel file. It is also possible to save the UDI product data as a draft and publish it in the software once it has been completed. Publishing in the software means that the product is prepared and fully validated for further transmission to EUDAMED. Before the data is loaded into EUDAMED, it is checked in mytracekey in accordance with the EUDAMED Business Rules. Only when all data meets the formal criteria can it be loaded into EUDAMED. If the system detects that data does not comply with the EUDAMED Business Rules, it issues corresponding error messages on the system side. For example, in the case of missing data or an incorrect data format. After publication, the product data is versioned, adjusted with each change and re-versioned.

  The manual entry of product data is possible via a data mask in the mytracekey UDI Manager. The data mask indicates which data must be entered according to the selected product template. In addition, a description is provided for each product field, making it easy to navigate through the manual data entry. The data entered can be saved as a draft at any time. Publication in mytracekey UDI Manager is only possible after successful validation.

  Via a pre-configured Excel spreadsheet that can be downloaded from the system, the product data can also be imported collectively into mytracekey UDI Manager. The

EUDAMED Business Rules Check is carried out during the upload. If the import is successful, the product data is saved as drafts and can subsequently be published in the software.

After successful publication of the product data in mytracekey UDI Manager, it can be downloaded as an XML file and uploaded to EUDAMED using the XML bulk upload function. Exporting the products in an Excel file is not available.

- **Help**
  The user has access to the mytracekey Self Service Portal. This portal contains all training documents and supports the user in using the software. Onboarding and further use of the system are based on the user guide and the associated FAQs.

2.2. Functions of "mytracekey UDI Manager BASIC"

The customer receives a single tenant in our multi-tenant system. mytracekey UDI Manager BASIC includes access to one tenant in the production environment (PRD).

Each tenant in the UDI Manager BASIC version contains the following apps and associated functions:

- **User Profile**
  The user can edit their own user profile and the user settings. Here, for example, the password can be changed or the system language set.
- **Start**
  Home page of the mytracekey UDI Manager software.

- **People**
  The main user (admin) can invite any number of additional users to the software via the People app. This is done via the e-mail address of the persons to be invited. In addition, preset roles can be assigned to each user. The assigned roles determine which functions (apps) are accessible to the respective user (role concept). Admin and UDI Data Manager are available as roles. Additional, application-based authorizations can also be set for each user.
  The following preset roles are available for UDI Manager BASIC:

UDI Data Manager

Apps
- Start
- Products
- Help

Tasks
- Configure and manage products
- Manage product hierarchy
- Import products
- Report products

Admin

Apps
- Start
- People
- Company Setup
- Help

Tasks
- User Administration
- Administration of Company Master Data

- **Company Setup**

  In this app, the mandatory company data for EUDAMED can be stored. Additionally, one authority can be configured.

- **Products**

  In this app, the UDI product data can be managed. For this purpose, product templates for the following regulations are stored in mytracekey UDI Manager: MDR, MDD, IVDR, IVDD, AIMDD. The UDI product data can be entered manually into the software or imported collectively in an Excel file. It is also possible to save the UDI product data as a draft and publish it in the software once it has been completed. Publishing in the software means that the product is prepared and fully validated for further transmission to EUDAMED. Before the data is loaded into EUDAMED, it is checked in mytracekey in accordance with the EUDAMED Business Rules. Only when all data meets the formal criteria can it be loaded into EUDAMED. If the system detects that data does not comply with the EUDAMED Business Rules, it issues corresponding error messages on the system side. For example, in the case of missing data or an incorrect data format. After publication, the product data is versioned, adjusted with each change and re-versioned.

  The manual entry of product data is possible via a data mask in the mytracekey UDI Manager. The data mask indicates which data must be entered according to the selected product template. In addition, a description is provided for each product field, making it easy to navigate through the manual data entry. The data entered can be saved as a draft at any time. Publication in mytracekey UDI Manager is only possible after successful validation.

  Via a pre-configured Excel spreadsheet that can be downloaded from the system, the product data can also be imported collectively into mytracekey UDI Manager. The

EUDAMED Business Rules Check is carried out during the upload. If the import is successful, the product data is saved as drafts and can subsequently be published in the software.

After successful publication of the product data in mytracekey UDI Manager, it can be downloaded as an XML file and uploaded to EUDAMED using the XML bulk upload function. Exporting the products in an Excel file is not available.

- **Help**
  The user has access to the mytracekey Self Service Portal. This portal contains all training documents and supports the user in using the software. Onboarding and further use of the system are based on the user guide and the associated FAQs.

2.3. Functions of "mytracekey UDI Manager FULL

The customer receives a single tenant in our multi-tenant system. mytracekey UDI Manager FULL includes access to one tenant in the production environment (PRD) and one tenant in the test environment (SBX).

Each tenant in the UDI Manager FULL version contains the following apps and associated functions:

- **User Profile**
  The user can edit their own user profile and user settings. Here, for example, the password can be changed or the system language set.

- **Start**
  Home page of the mytracekey UDI Manager software.

- **People**
  The main user (admin) can invite any number of additional users to the software via the People app. This is done via the e-mail address of the persons to be invited. In addition, preset roles can be assigned to each user. The assigned roles determine which functions (apps) are accessible to the respective user (role concept). Admin and UDI Data Manager are available as roles. Additional, application-based authorizations can also be set for each user.
  The following preset roles are available for UDI Manager FULL:

UDI Data Manager

Apps
- Start
- Products
- Reports
- Help

Tasks
- Configure and manage products
- Manage product hierarchy
- Import and export products
- Report products

Admin

Apps
- Start
- People
- Company Setup
- Docs
- Audit Trail
- Help

Tasks
- User Administration
- Administration of Company Master Data
- Set up of M2M Connection
- Download of Validation Documentation

- **Company Setup**

  The mandatory company data for EUDAMED can be stored in this app. Additionally, one authority can be configured. If the M2M add-on is purchased, the settings for the M2M connection can be stored here.

- **Products**

  In this app, the UDI product data can be managed. Product templates for the following regulations are stored in mytracekey UDI Manager for this purpose: MDR, MDD, IVDR, IVDD, AIMDD. The UDI product data can be entered manually in the software or imported collectively in an Excel file. It is also possible to save the UDI product data as a draft and publish it in the software once it has been completed. Publishing in the software means that the product is prepared and fully validated for further transmission to EUDAMED. Before the data is loaded into EUDAMED, it is checked in mytracekey in accordance with the EUDAMED Business Rules. Only when all data meets the formal criteria can it be loaded into EUDAMED. If the system detects that data does not comply with the EUDAMED Business Rules, it issues corresponding error messages on the system side. For example, in the case of missing data or an incorrect data format. After publication, the product data is versioned, adjusted with each change and re-versioned.

The manual entry of product data is possible via a data mask in the mytracekey UDI Manager. The data mask indicates which data must be entered according to the selected product template. In addition, a description is provided for each product field, making it easy to navigate through the manual data entry. The data entered can be saved as a draft at any time. Publication in mytracekey UDI Manager is only possible after successful validation.

Via a pre-configured Excel spreadsheet that can be downloaded from the system, the product data can also be imported collectively into mytracekey UDI Manager. The EUDAMED Business Rules Check is carried out during the upload. If the import is successful, the product data is saved as drafts and can subsequently be published in the software.

After successful publication of the product data in mytracekey UDI Manager, it can be downloaded as an XML file and uploaded to EUDAMED using the XML bulk upload function. Exporting the products in an Excel file is available.

- **Reports**
  In the Reports App the Task Manager is included. The Task Manager is part of the mytracekey UDI Manager FULL compliance package and supports the user in working with the software by showing the user which product data must be reported to EUDAMED. Based on the tasks displayed, the user can create corresponding XML documents (reports) in EUDAMED format for product data. The reports are provided with a time stamp when they are created and can be found in the overview. The user can download these reports or, in combination with the M2M add-on, send them directly to EUDAMED via the interface. If the reports are sent via the M2M connection, the transmission status is displayed to the user and can be viewed permanently for audits at any time.

- **Docs**
  The user has access to the validation documentation of the software as part of the compliance package of this subscription.

- **Audit Trail**
  The Audit Trail (app) is part of the compliance package. Every step that our customers take in the software is stored in the audit trail. In this way, it remains traceable in the long term who used which functions, when, and reported or changed data.

- **Help**
  The user has access to the mytracekey Self Service Portal. This portal contains all training documents and supports the user in using the software. Onboarding and further use of the system are based on the user guide and the associated FAQs.

2.3.1. Add-On: "M2M Connection (Machine-to-Machine)"

The M2M connection (machine-to-machine) is a direct interface between mytracekey and EUDAMED. It allows large volumes of data to be exchanged quickly and easily with EUDAMED. The step of manually transferring XML files from one system to the other is no longer necessary.

This add-on is only available in mytracekey UDI Manager FULL and must also be added to the contract.

2.4. Functions of "mytracekey UDI Manager PREMIUM

The customer receives a single tenant in our multi-tenant system. mytracekey UDI Manager PREMIUM includes access to one tenant in the production environment (PRD) and one tenant in the test environment (SBX).

Each tenant in the UDI Manager PREMIUM version contains the following apps and associated functions:

- **User Profile**
  The user can edit their own user profile and user settings. Here, for example, the password can be changed or the system language set.

- **Start**
  Home page of the mytracekey UDI Manager software.

- **People**
  The main user (admin) can invite any number of additional users to the software via the People app. This is done via the e-mail address of the persons to be invited. In addition, preset roles can be assigned to each user. The assigned roles determine which functions (apps) are accessible to the respective user (role concept). Admin and UDI Data Manager are available as roles. Additional, application-based authorizations can also be set for each user.
  The following preset roles are available for UDI Manager PREMIUM:

  UDI Data Manager
      Apps
  - Start
  - Products
  - Reports
  - Help

      Tasks
  - Configure and manage products
  - Manage product hierarchy
  - Import and export products
  - Report products

  Admin
      Apps
  - Start
  - People
  - Company Setup
  - Docs
  - Audit Trail
  - Help

      Tasks

- User Administration
- Administration of Company Master Data
- Set up of M2M Connection
- Download of Validation Documentation

- **Company Setup**
  The mandatory company data for EUDAMED can be stored in this app. Additionally, up to three authorities with M2M connectivity can be configured.

- **Products**

  In this app, the UDI product data can be managed. Product templates for the following regulations are stored in mytracekey UDI Manager for this purpose: MDR, MDD, IVDR, IVDD, AIMDD. The UDI product data can be entered manually in the software or imported collectively in an Excel file. It is also possible to save the UDI product data as a draft and publish it in the software once it has been completed. Publishing in the software means that the product is prepared and fully validated for further transmission to EUDAMED. Before the data is loaded into EUDAMED, it is checked in mytracekey in accordance with the EUDAMED Business Rules. Only when all data meets the formal criteria can it be loaded into EUDAMED. If the system detects that data does not comply with the EUDAMED Business Rules, it issues corresponding error messages on the system side. For example, in the case of missing data or an incorrect data format. After publication, the product data is versioned, adjusted with each change and re-versioned.

  The manual entry of product data is possible via a data mask in the mytracekey UDI Manager. The data mask indicates which data must be entered according to the selected product template. In addition, a description is provided for each product field, making it easy to navigate through the manual data entry. The data entered can be saved as a draft at any time. Publication in mytracekey UDI Manager is only possible after successful validation.

  Via a pre-configured Excel spreadsheet that can be downloaded from the system, the product data can also be imported collectively into mytracekey UDI Manager. The EUDAMED Business Rules Check is carried out during the upload. If the import is successful, the product data is saved as drafts and can subsequently be published in the software.

  After successful publication of the product data in mytracekey UDI Manager, it can be downloaded as an XML file and uploaded to EUDAMED using the XML bulk upload function. Exporting the products in an Excel file is available.

- **Reports**
  In the Reports App the Task Manager is included. The Task Manager is part of the compliance package and supports the user in working with the software by showing the user which product data must be reported to EUDAMED. Based on the tasks displayed, the user can create reports for EUDAMED and send them directly to EUDAMED via the

interface. If the reports are sent via the M2M connection, the transmission status is displayed to the user and can be viewed permanently for audits at any time.

- **Docs**
  The user has access to the validation documentation of the software as part of the compliance package of this subscription.

- **Audit Trail**
  The Audit Trail (app) is part of the compliance package. Every step that our customers take in the software is stored in the audit trail. In this way, it remains traceable in the long term who used which functions, when, and reported or changed data.

- **Help**
  The user has access to the mytracekey Self Service Portal. This portal contains all training documents and supports the user in using the software. Onboarding and further use of the system are based on the user guide and the associated FAQs.

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 BASIC, FULL, 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 both 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 EUDAMED in accordance with the EUDAMED 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*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 (except FREE and BASIC), 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 some of the UDI Manager packages. 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 monthly prices of the subscription versions are made up of a basic fee and a usage-based price component. The amount of the monthly basic 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. Both 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 takes place with the billing of the monthly basic fee at the end of each contract month. If the initially booked inclusive number of UDIs is not reached, no credit will be issued.

Below are the current prices for the bookable subscription models and add-on options:

8.1.1. mytracekey UDI Manager FREE

Basic fee per month: €0

Contract duration: monthly

UDIs included: 10

Cost per additionally managed UDI per month: not available

Including features: own tenant in the mytracekey system, self-service portal, product templates (MDR, MDD, IVDR, IVDD, AIMDD), authority configuration for 1 SRN, EUDAMED business rule validation, Excel import function, XML bulk reporting function, access to the test environment (SBX), audit trail, validation documents

8.1.2. mytracekey UDI Manager BASIC

Basic fee per month: €79

Contract duration: monthly

UDIs included: 100

Cost per additionally managed UDI per month: €0,90

Including features: own tenant in the mytracekey system, self-service portal, product templates (MDR, MDD, IVDR, IVDD, AIMDD), authority configuration for 1 SRN, EUDAMED

business rule validation, Excel import function, XML bulk reporting function, access to the production environment (PRD)

8.1.3. mytrackey UDI Manager FULL

Basic fee per year: €1.188

Contract duration: annually

UDIs included: 100

Cost per additionally managed UDI per month: €0,04

Including features: own tenant in the mytracekey system, self-service portal, product templates (MDR, MDD, IVDR, IVDD, AIMDD), authority configuration for 1 SRN, EUDAMED business rule validation, Excel import function, Excel export function, XML bulk reporting function, access to the production environment (PRD), test environment (SBX), task manager, audit trail, validation documents, technical support

Additionally, it is possible to book the M2M add-on (direct interface to EUDAMED) at a fixed monthly price.

8.1.4.   mytracekey UDI Manager PREMIUM

Basic fee per year: €2.148

Contract duration: annually

UDIs included: 300

Cost per additionally managed UDI per month: €0,04

Including features: own tenant in the mytracekey system, self-service portal, product templates (MDR, MDD, IVDR, IVDD, AIMDD), authority configuration for up to 3 SRN, EUDAMED business rule validation, Excel import function, Excel export function, XML bulk reporting function, M2M reporting function, access to the production environment (PRD), test environment (SBX), task manager, audit trail, validation documents, technical support

8.1.5. M2M Add-on

Fixed price per year: €600

Contract duration: annually

The interface enables data to be uploaded directly from the mytracekey UDI Manager FULL to the EUDAMED UDI module.

All prices quoted here do not include VAT. The applicable VAT will be shown and charged separately during the purchase 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.