Medical Device Track and Trace System in Turkey Cooperated by
Turkish Medicines and Medical Devices Agency and
The Scientific and Technological Research Council of Turkey

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Presentation Topics

• Overview
  - Project Purpose
  - Achievements
  - Scope

• Dissemination Activities
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Project Purpose

- To keep record of medical devices and cosmetic products
- To establish a **National and Original infrastructure** which meets performance requirements to keep track of products
- To contribute to ensuring **patient safety** and protection of **public health**
- To provide an infrastructure to ensure healthy and efficient execution of inspection services
- To ensure rapid measures are taken against possible risks to occur during use of the products

provides an infrastructure to track medical devices and cosmetic products manufactured in our country or imported from the production band to the place where they are sold and used.
Achievements

- Secure Product Access
- Efficient Audit
- Identification of Health Policies
- Struggle Against Unrecorded Economy
Product Tracking System (ÜTS) Overview

- **Manufacturer / Importer**: Product registration and sending documents to the system
- **TITCK**: Testing the product registration and the documents
- **Manufacturer / Importer**: Sending the production/importation to the system
- **Places of Application / Sale**: Adding of product usage and sales returns
- **Distributor / Warehouse**: Sending product movements
- **TITCK**: Realising of audit and retracts activities
- **Citizen**: Query of registered products
Product Management

**Medical Device**

1. Adding documents by the Manufacturer / Importer Company
2. Controlling documents by TITCK
3. Adding product record by the Manufacturer / Importer Company
4. Controlling the record by TITCK
5. Registered product

**Cosmetic**

1. Adding formula by the Manufacturer / Importer Company
2. Adding product record by the Manufacturer / Importer Company
3. Controlling the record by TITCK
4. Registered product
Single and Lot Based Tracking

Single Tracking

Single product

Lot Based Tracking

Single Product Group
Single Product Traceability

- 7/24 end-to-end single product tracking and monitoring
- Varying routes in product movements
- Different movement types and codes of conduct
- Partner system diversity and number

~ 1 billion/day
~ 400 billion/year
Clinical Engineering Processes

Scenarios will be developed according to the Clinical Engineering Legislation to be issued.
Organization, User and (Dynamic) Authority Management
Business Intelligence

SECTOR
To access comprehensive information on single products

T.R. MINISTRY OF HEALTH
To contribute to determination of efficient health policies

CITIZEN
To access information on safe products

INSPECTION TEAMS
To actively contribute to risk based inspection and withdrawal

The Global Language of Business
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Citizen Oriented Services
Citizen Oriented Services
ÜTS Users

**PRODUCT MANAGEMENT**
- Manufacturer and Importer Companies
  - Medical Device Manufacturers / Importers
  - Cosmetic Manufacturers / Importers
- Public Organizations
  - Turkish Drug and Medical Device Institution (TITCK)
  - Social Security Institution (SGK)
  - National Poison Information Center (UZEM)

**PRODUCT MOVEMENTS**
- Manufacturer and Importer Companies
- Distributors / Warehouses
- Places of Use
- Places of Sale
- Public Organizations
  - Turkish Drug and Medical Device Institution (TITCK)
  - Social Security Institution (SGK)
  - Turkish Public Hospitals Authority (TJKH)
  - Turkish Public Health Authority (THSK)

**CLINICAL ENGINEERING**
- Maintenance and Calibration Companies
- Public Organizations
  - Turkish Drug and Medical Device Institution (TITCK)
  - Social Security Institution (SGK)
  - Turkish Public Hospitals Authority (TJKH)
  - Turkish Public Health Authority (THSK)
  - Turkish Atomic Energy Authority (TAEK)

**MARKET SURVEILLANCE AND INSPECTION**
- Public Organizations
  - Turkish Drug and Medical Device Institution (TITCK)
  - Social Security Institution (SGK)
  - T.R. Ministry of Economy
  - T.R. Ministry of Customs and Trade
Integrations

15 System Integration

- **MERSİS**: Central Registration System
- **ESBİS**: Tradesmen and Craftsmen Information System
- **MERNİS**: Central Population Administration System
- **ÇKYS**: Core Resource Management System
- **MKYS**: Material Resource Management System
- **HBYS**: Hospital Information Management System
- **e-Nabız**: e-Pulse Portal

- **EUDAMED**: The European Databank on Medical Devices
- **National PGD Database**: Market Surveillance and Inspection
- **GMDN**: Global Medical Device Nomenclature
- **VEDOP**: Tax Administration Automation Project
- **e-Devlet**: e-Government Gate
- **TİTÇK EBYS**: Electronic Information Management System

- **MEDULA**: Medical Courier
- **EKAP**: Electronic Public Procurement Platform
- **TİTÇK EBYS**: Electronic Information Management System
- **e-Nabız**: e-Pulse Portal

- **EUDAMED**: The European Databank on Medical Devices
- **CPNP**: Cosmetic Products Notification Portal
- **National PGD Database**: Market Surveillance and Inspection

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ÜTS Timeline

Product Management Module (Medical Device) is put to use in the test environment.

1 March 2016

Product Management Module (Cosmetics) is put to use in the production environment.

2 March 2016

Product Movements Module (Medical Device) is put to use in the test environment.

28 March 2016

UTS-v3.5.0

25 May 2016

UTS-v5.1.0

3 October 2016

Product Management Module (Medical Device) will be put to use in the production environment.
ÜTS Portal

- Information about the new versions, training materials, news on workshops conducted and up to date information about the project are published in the portal.

http://uts.saglik.gov.tr/
Contact Information

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THANK YOU

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