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

MD Yalçın Soysal, Head of Medical Device Registration and Coordination Department in Turkish Medicines and Medical Devices Agency,
Ankara, TURKİYE
October 19, 2017
Presentation Topics

• Overview
  - ÜTS Purpose
  - Achievements
  - Scope
• Dissemination Activities
Poly Implant Prothesis (PIP) Incident

In 2011, France Authorities have found out that industrial silicon was being used instead of medical grade silicone in implants (owner: Jean-Claude Mas)

Unable to indicate which patients were implanted one of these

Implanted in 300,000 women, in 65 countries
ÜTS Purpose

- To keep record of medical devices and cosmetic products
- To establish a **National and Original infrastructure** that can keep track of products
- **Patient safety** and protection of **public health**
- Efficient execution of **inspection services**
- Rapid measures for possible risks occur during use of the products

provides an infrastructure to track medical devices manufactured or imported to the place where they are sold and used.
ÜTS Timeline

- 7 January 2014: Project Start
- 1 March 2016: Product Management Module (Cosmetics)
- 12 June 2017: Product Management Module (Medical Device)
- 11 September 2017: Track and Monitoring Module (Medical Device)
Achievements

- Secure Product Access
- Efficient Audit
- Identification of Health Policies
- Struggle Against Unrecorded Economy
Scope

25 Modules
(8 Module Groups)

Tracking and Monitoring
- Product Movements Module
- Product Withdrawal Module

Citizen Oriented Services
- Product Inquiry Module
- Registered On-Person Product Inquiry Module
- Complaint Reporting Module
- Maintenance and Calibration Inquiry Module

Supporting Functions
- Document and Certificate Management Module
- Reference Areas Management
- Log Management Module
- Announcement Module
- Scheduled Tasks Module

Market Surveillance and Inspection (PGD) and Warning
- Inspection Activities Module
- Warning Module

User, Organization and Authority Management
- User Management Module
- Organization Management Module
- Authority Management Module

Clinical Engineering
- Maintenance and Repair Management Module
- Calibration Management Module
- Technical Personnel Certification Module
- Technical Service Management Module
- Calibration Organization Management Module

Business Intelligence
- Predefined Reporting Module
- Map Assisted Reporting Module

The Global Language of Business
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Steps of ÜTS

• First step is **registration of movement points**; hospital, manufacturer, distributor, warehouse, pharmacy, medical market... expected (50,000 movement points)

• Second step is **registration of document** like CE, DC, IFU.. expected (150,000 documents)

• **Registration of medical devices** according to UDI standard also with **picture** expected (4,000,000 medical devices)

• **Movements notification** of products expected (1 billion/day)

• **End point users** (devices implanted or used patients with identity number)
Product Track&Trace System (ÜTS) Overview

- **Manufacturer / Importer**
  - Sending documents and product information

- **TITCK**
  - Examining the documents and product registration

- **Manufacturer / Importer**
  - Sending the notification of production/importation

- **Application / Sale Places**
  - Adding of product usage and sales returns

- **Distributor / Warehouse**
  - Sending product movements

- **TITCK**
  - Realising of audit and recall activities

- **Clinical Engineering**
  - Calibration, maintenance operations

- **Citizen**
  - Query of registered products

**Clinical Engineering**
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
- Stake holders diversity and number
Clinical Engineering Processes
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
• With the mobile application (IOS, Android), ordinary citizens will be able to query sold or used medical device specified information. (label, packaging and calibration information, safety for use or not, localization, product visuals etc.)
ÜTS Users

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

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

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

MARKET SURVEILLANCE AND INSPECTION
- Public Organizations
  - Turkish Drug and Medical Device Institution (TİTCK)
  - Social Security Institution (SGK)
  - T.R. Ministry of Economy
  - T.R. Ministry of Customs and Trade
# External Systems

## 15 System Integration

<table>
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<tr>
<th>System</th>
<th>Description</th>
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<tbody>
<tr>
<td>MERSİS</td>
<td>Central Registration System</td>
</tr>
<tr>
<td>ESBİS</td>
<td>Tradesmen and Craftsmen Information System</td>
</tr>
<tr>
<td>MERNİS</td>
<td>Central Population Administration System</td>
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<tr>
<td>ÇKYS</td>
<td>Core Resource Management System</td>
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<tr>
<td>MKYS</td>
<td>Material Resource Management System</td>
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<tr>
<td>HBYS</td>
<td>Hospital Information Management System</td>
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<tr>
<td>e-Nabız</td>
<td>e-Pulse Portal</td>
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<tr>
<td>EUDAMED</td>
<td>The European Databank on Medical Devices</td>
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<tr>
<td>National PGD Database</td>
<td>Market Surveillance and Inspection</td>
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<tr>
<td>GMDN</td>
<td>Global Medical Device Nomenclature</td>
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<tr>
<td>VEDOP</td>
<td>Tax Administration Automation Project</td>
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<tr>
<td>e-Devlet</td>
<td>e-Government Gate</td>
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<tr>
<td>TİTCK EBYS</td>
<td>Electronic Information Management System</td>
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<tr>
<td>MEDULA</td>
<td>Medical Courier</td>
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<tr>
<td>EKAP</td>
<td>Electronic Public Procurement Platform</td>
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<tr>
<td>TİTCK EBYS</td>
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<td>CPNP</td>
<td>Cosmetic Products Notification Portal</td>
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<td>National PGD Database</td>
<td>Market Surveillance and Inspection</td>
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<td>Optics (Lens and Spectacles)</td>
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<td>Active Implantable Medical Devices</td>
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<td>Class I</td>
<td>01.01.2022</td>
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ÜTS Launch Date: **12.06.2017**
• 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/
Eyes of ÜTS on you !!..
Contact Information

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THANK YOU