Implementation and Dissemination of Medical Device Traceability in Turkey

Turkish Medicines and Medical Devices Agency and
The Scientific and Technological Research Council of Turkey

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Presentation Topics

• Overview
  - ÜTS Purpose
  - Achievements
  - Scope

• Dissemination Activities
Introductory Video of ÜTS
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**
- Taking rapid measures for possible risks occurring during use of the products

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

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

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

Business Intelligence
- Predefined Reporting Module
- Map Assisted Reporting Module

The Global Language of Business
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Product Tracking 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 Product Identifier

Barcode + Serial No + Lot No = Single Product

Barcode No: 8691234567890
Serial No: 12375647300127398294
Lot No: 234
Date of Production: 31.12.2017
Date of Expiry: 31.12.2021
Serial and Lot Based Tracking

Serial Based Tracking

Single Product

Lot Based Tracking

Single Product Group
Single Product Traceability
TÜS Timeline - 1

- **Project Started**: 11 October 2017
- **1 March 2016**: Medical device company, documentation and product registration procedures brought into use
- **12 June 2017**: Cosmetic product management brought into use
- **11 September 2017**: Starting legal proceedings for optical medical devices

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ÜTS Timeline – 2

Market surveillance, audit and warning procedures brought into use

11 October 2017

Tracking started for 90/385/EEC medical devices

2 July 2018

Tracking started for Class III medical devices

1 October 2018

27 December 2018

Project Completed
## ÜTS Tracking Transition Plan

<table>
<thead>
<tr>
<th>MD Class</th>
<th>Start Date</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optics</td>
<td>11.09.2017</td>
<td>Started</td>
</tr>
<tr>
<td>AIMD</td>
<td>02.07.2018</td>
<td>Started</td>
</tr>
<tr>
<td>Class III</td>
<td>01.10.2018</td>
<td>Started</td>
</tr>
<tr>
<td>Class IIb</td>
<td>2019</td>
<td>Planned</td>
</tr>
<tr>
<td>Class IIa</td>
<td>2019</td>
<td>Planned</td>
</tr>
<tr>
<td>Class I</td>
<td>2019</td>
<td>Planned</td>
</tr>
</tbody>
</table>
As of October 2018:

<table>
<thead>
<tr>
<th>Company</th>
<th>QTY</th>
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<tbody>
<tr>
<td>Manufacturer/Importer/Dealer</td>
<td>6,300</td>
</tr>
<tr>
<td>Healthcare Providers</td>
<td>1,554</td>
</tr>
<tr>
<td><strong>Total (including others)</strong></td>
<td><strong>29,315</strong></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Document</th>
<th>QTY</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE Certificates</td>
<td>13,849</td>
</tr>
<tr>
<td>DoC</td>
<td>95,719</td>
</tr>
<tr>
<td>IFU</td>
<td>71,445</td>
</tr>
<tr>
<td><strong>Total (including others)</strong></td>
<td><strong>189,965</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product</th>
<th>QTY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>1,845,790</td>
</tr>
<tr>
<td>Class IIa</td>
<td>259,918</td>
</tr>
<tr>
<td>Class IIb</td>
<td>460,697</td>
</tr>
<tr>
<td>Class III</td>
<td>225,919</td>
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<tr>
<td>IVD</td>
<td>39,871</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>2,902,134</strong></td>
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</table>
As of October 2018:
Total Movement Notification is **140,200,065**
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/
To Sum Up

- **2,9 Million**
  Registered Medical Device
  (October 2018)

- **50 Million**
  Unique Product
  (October 2018)

**ÜTS IN A DAY**

- **8 Million**
  Transaction

- **350,000**
  External System Query

- **550,000**
  Movement Notification

- **400**
  Document Record

- **15,000**
  Medical Device Record

- **250,000**
  Unique Product Record