



The Global Language of Business

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

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Ankara, TURKİYE

October 19, 2017

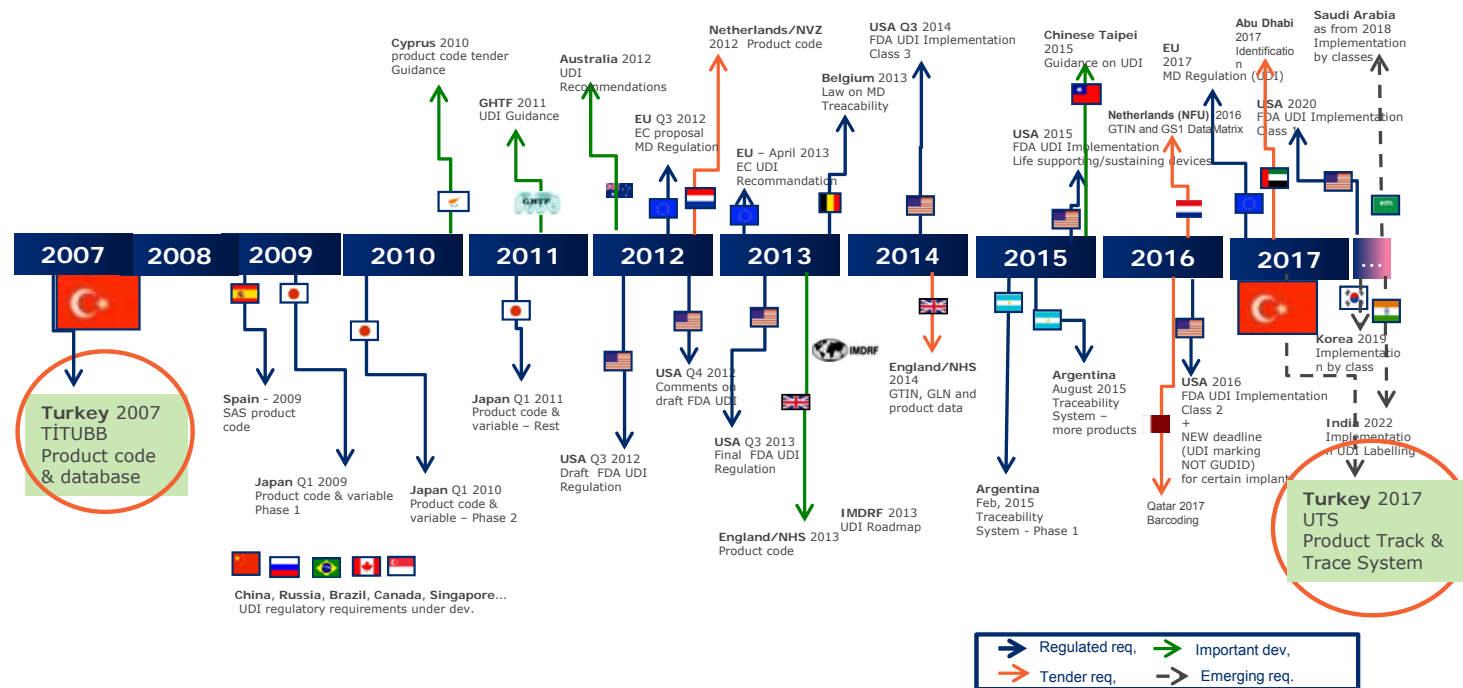
Presentation Topics



- Overview
 - ÜTS Purpose
 - Achievements
 - Scope
- Dissemination Activities

Medical Devices

Coding and Database Requirements





Poly Implant Prosthesis (PIP) Incident

In 2011, France Autorites 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

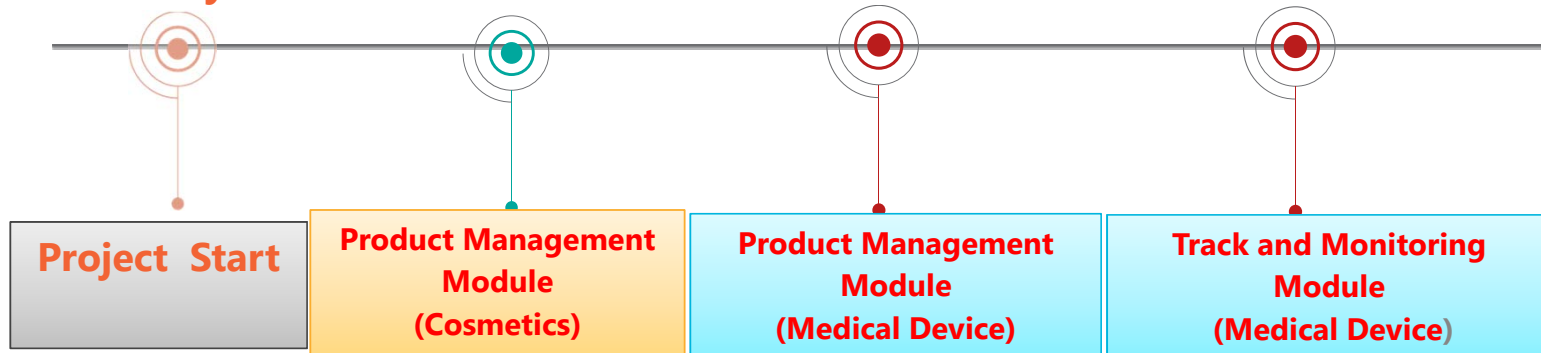


7 January 2014

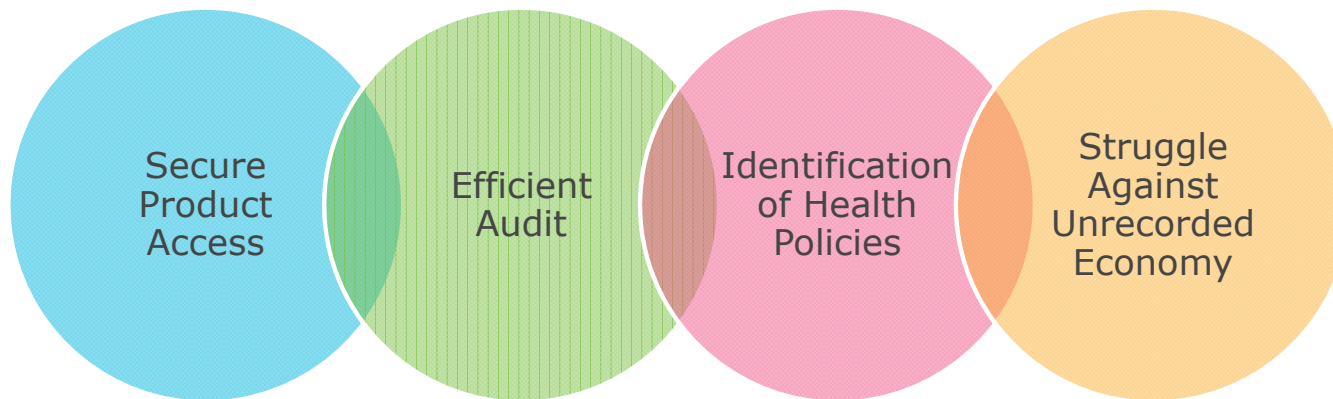
1 March 2016

12 June 2017

11 September 2017



Achievements



Scope

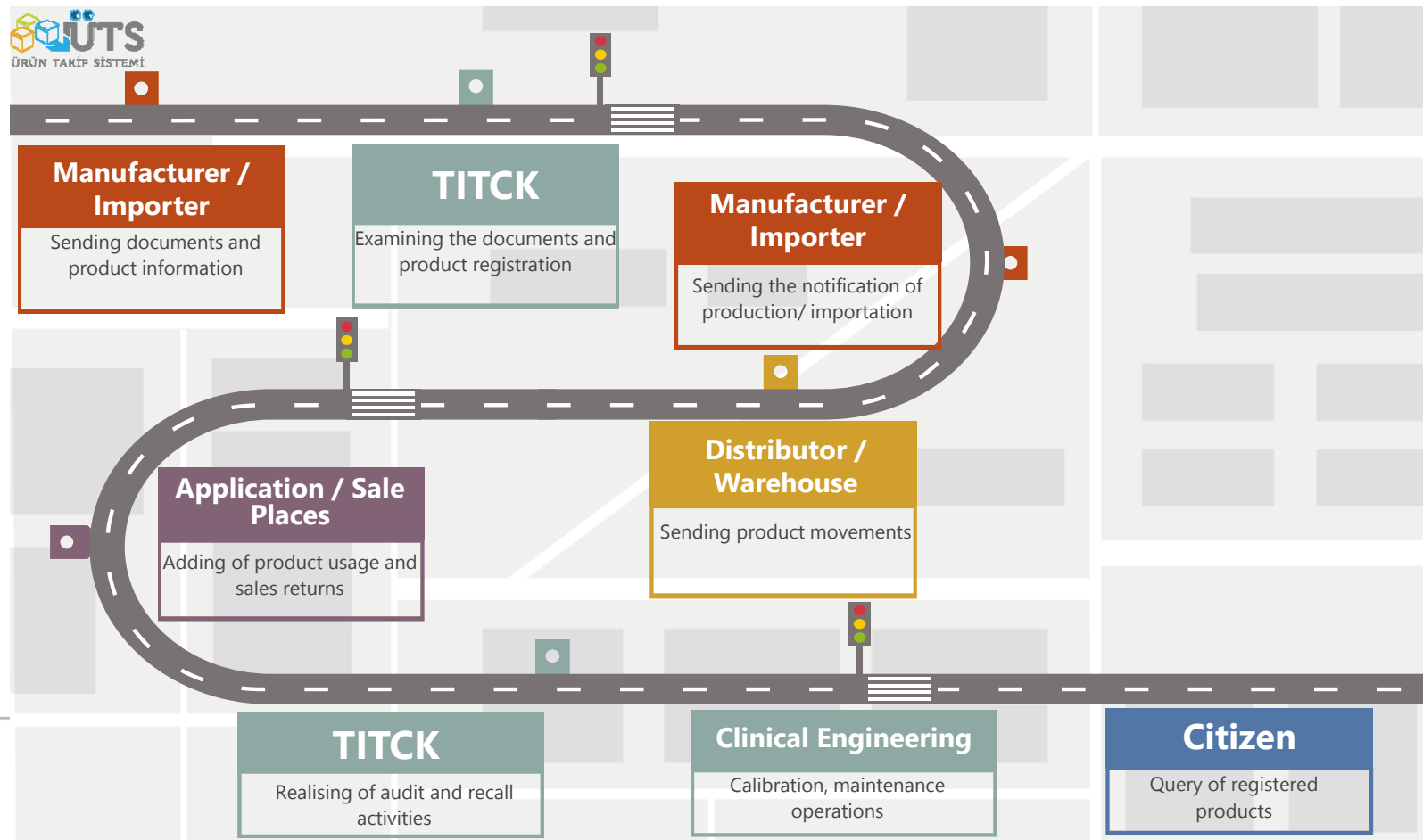


Steps of ÜTS



- 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

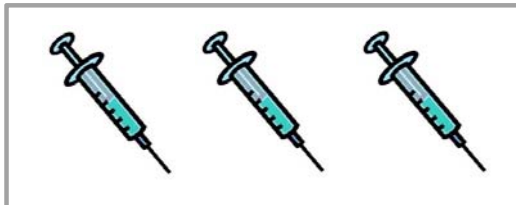


Single and Lot Based Tracking



Single Product

Single Tracking



Single Product Group

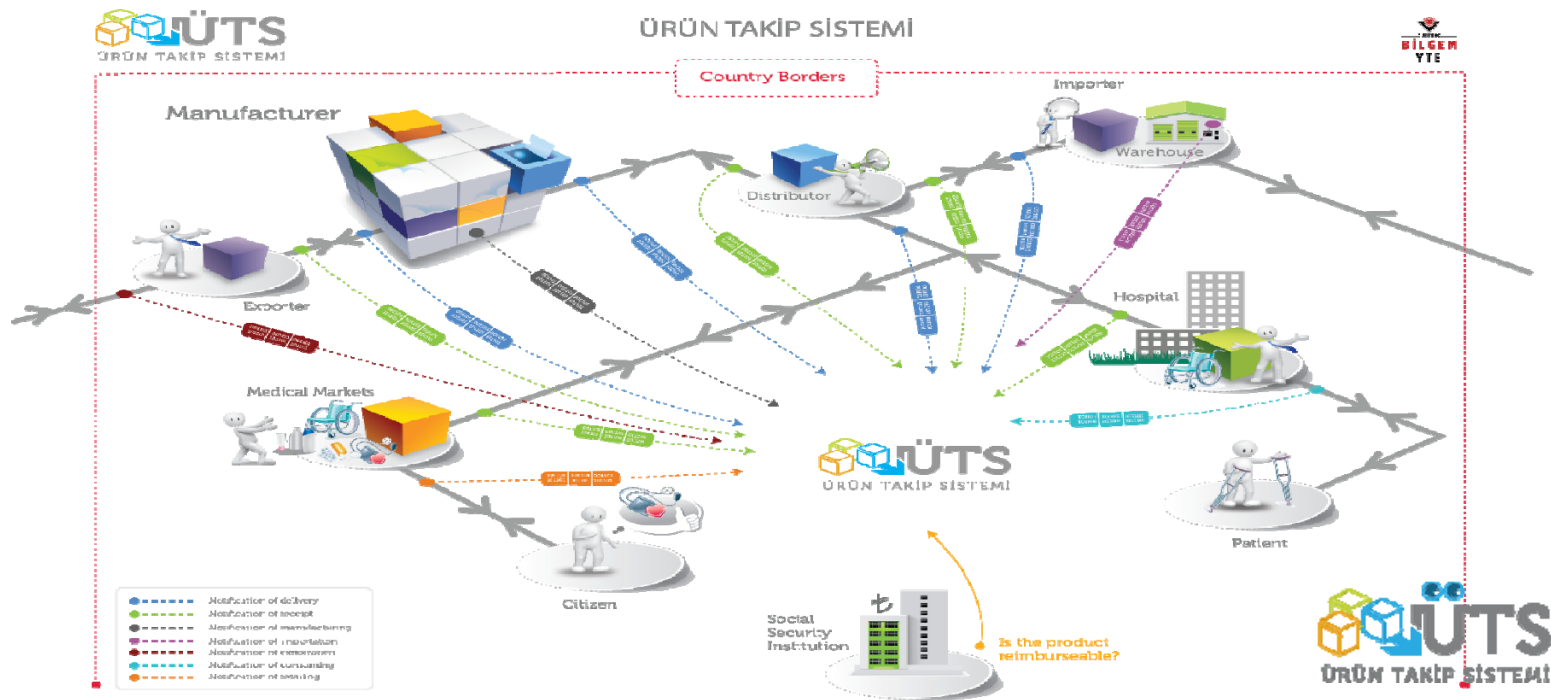
Lot Based Tracking



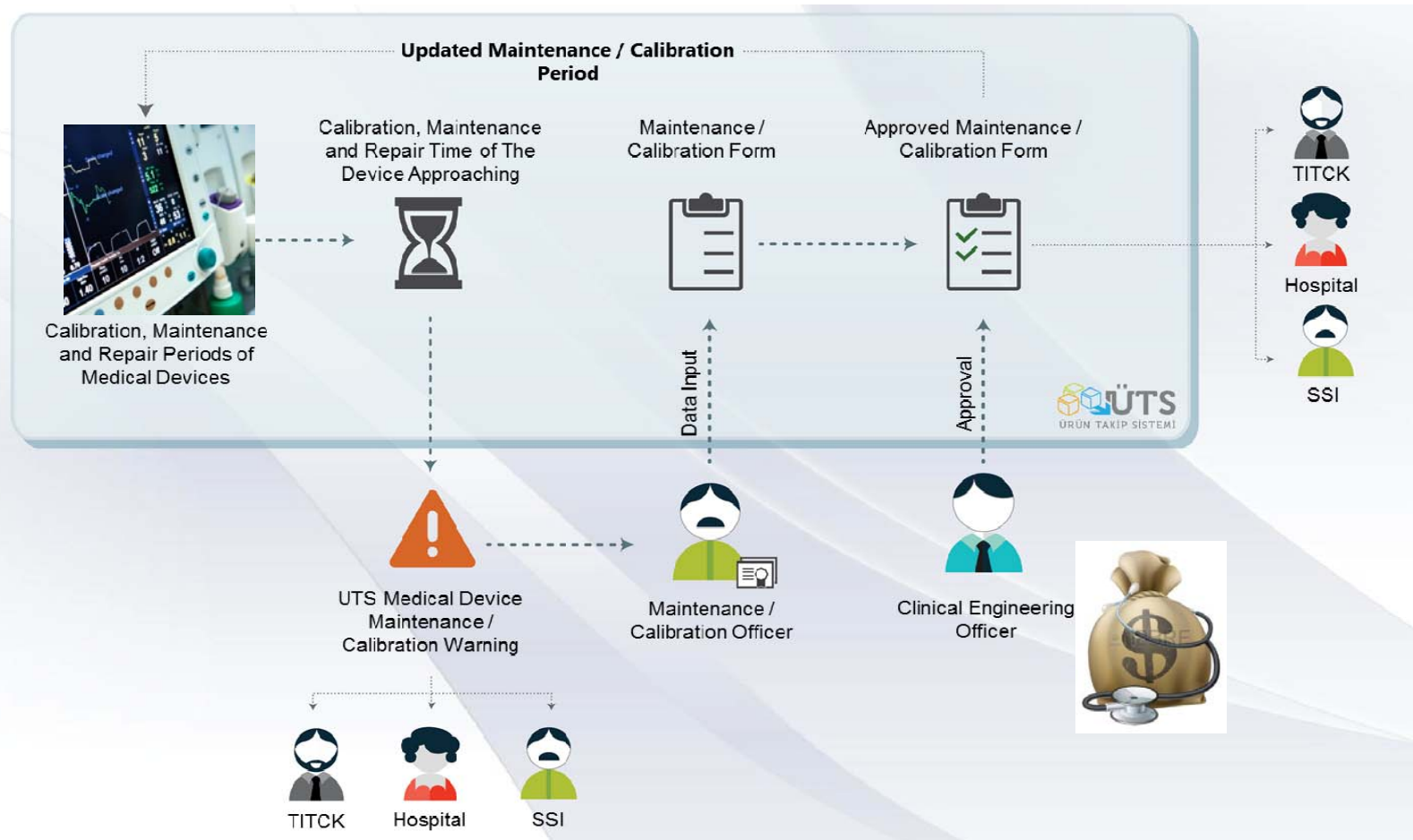
Single Product Traceability



- 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

ÜTS MOBILE APPLICATION



- 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)

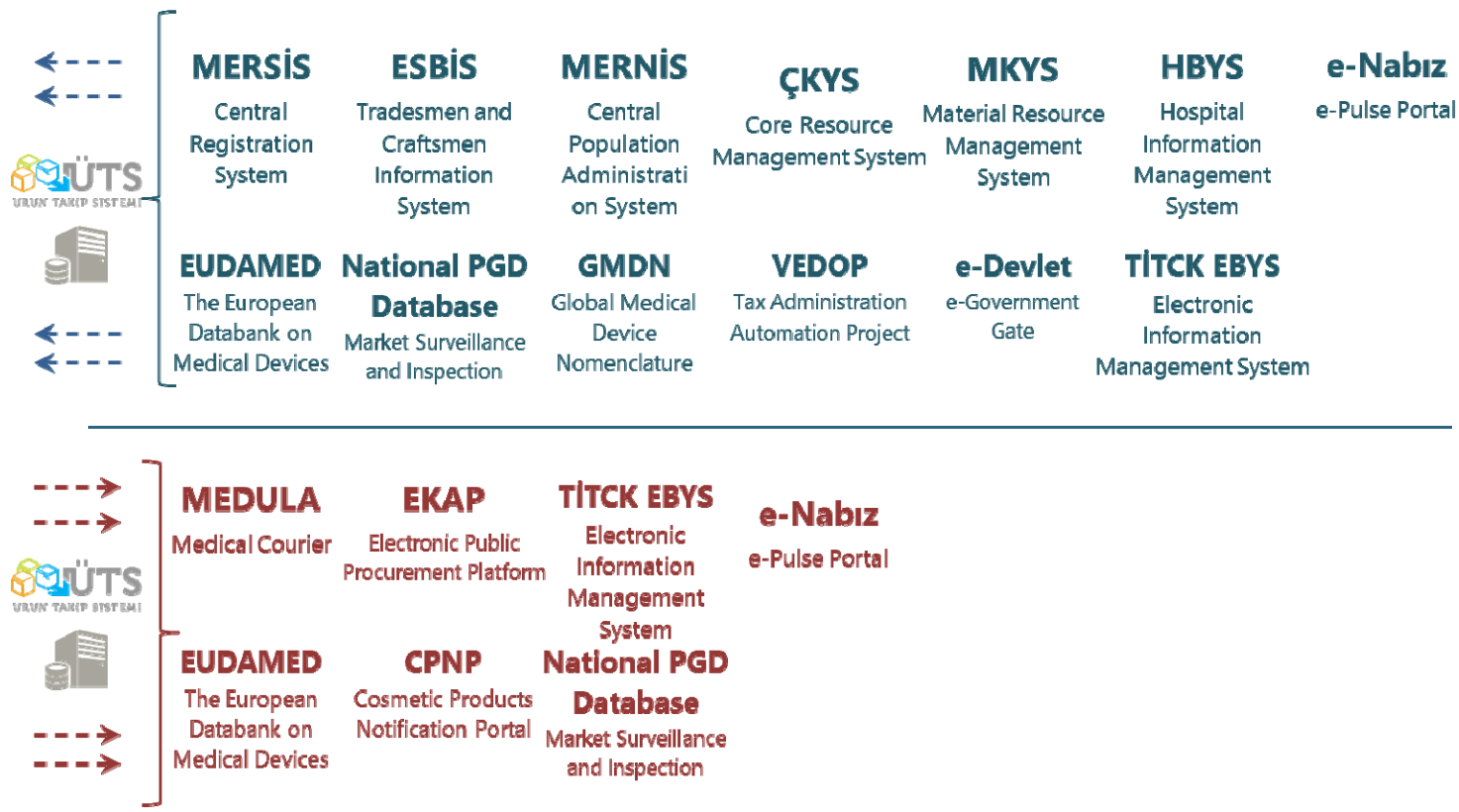
MARKET SURVEILLANCE AND INSPECTION

- **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



ÜTS Tracking Transition Plan Estimated



ÜTS Launch Date: **12.06.2017**

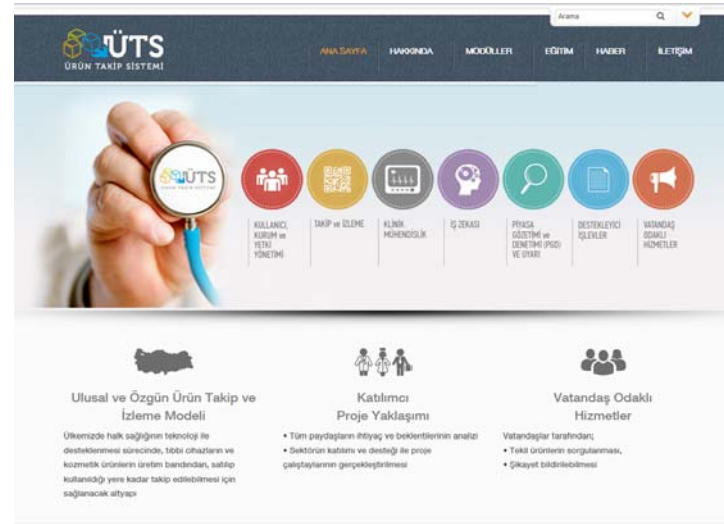
Optics (Lens and Spectacles)	11.09.2017					
Active Implantable Medical Devices		01.01.2018				
Class III			01.06.2018			
Class IIb				01.01.2019		
Class IIa					01.06.2019	52
Class I						01.01.2022

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/>





Eyes of ÜTS on you !!..



Contact Information



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THANK YOU



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