Tekil Cihaz Tanımlama Sistemi - Unique Device Identification System (UDI)

TÜRKİYE İLAÇ VE TIBBİ CİHAZ KURUMU

Tıbbi Cihazlar Dairesi
Müh. Funda ÖZDİLER ÇOPUR
E-mail: funda.ozdiler@titck.gov.tr

T.C. Sağlık Bakanlığı

T.C. Sağlık Bakanlığı
İlaç ve Tıbbi Cihaz Kurumu

KONULAR

- Avrupa ve ABD Tıbbi Cihaz Kaydı
- UDI (Tekil Cihaz Tanımlama Sistemi) nedir?-Etiket örnekleri
- Avrupa Komisyonu Tavsiye Kararı
- UDI Veri tabanları
- UDI Uygulama Takvimi

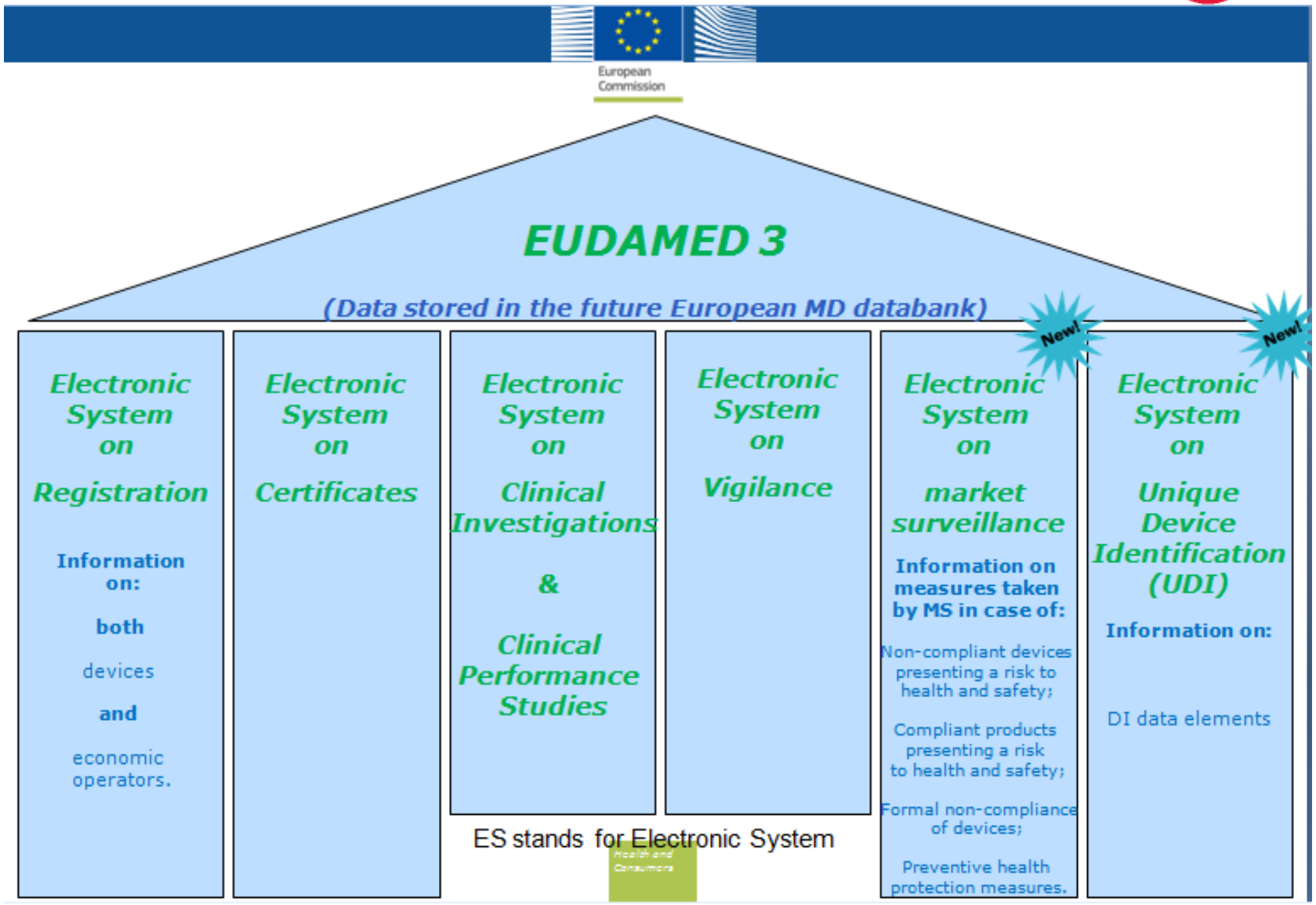
AVRUPA KAYIT SİSTEMLERİ

➢**Tekil bazlı takip yapılmamaktadır**

Günümüzde birçok ülkenin kendi tıbbi cihaz veri tabanı / kayıt sistemleri mevcut ancak bu farklılık ortak bir takip mekanizmasının oluşmasını engellemektedir. Her ne kadar Avrupa Birliği üye ülkeleri arasında (Türkiye' de dahil) ortak veri tabanı "Eudamed" kullanılsa da sistem bir takip mekanizmasından çok kayıt mekanizması haline gelmiştir.

➢**Takipte en büyük sıkıntı ortak bir terminoloji olmamasından kaynaklanmaktadır.**

EUDAMED


European Commission
EUDAMED 3
(Data stored in the future European MD databank)
Electronic System on Registration
Information on:
both
devices
and
economic operators.
Electronic System on Certificates
Electronic System on Clinical Investigations & Clinical Performance Studies
Electronic System on Vigilance
Electronic System on market surveillance
New!
Information on measures taken by MS in case of:
Non-compliant devices presenting a risk to health and safety;
Compliant products presenting a risk to health and safety;
Formal non-compliance of devices;
Preventive health protection measures.
Electronic System on Unique Device Identification (UDI)
New!
Information on:
DI data elements
ES stands for Electronic System

T.C. Sağlık
Bakanlığı
İlaç ve Tıbbi Cihaz
Kurumu

FDA's UDI Final Regulation

- 2007 FDA Amendments Act of 2007
- 2012 July 10th – UDI *Proposed* Regulation Publishes
- 2012 July – FDASIA provisions added
- 2012 November 7th – original comment period closes
- 2012 November 19th – FDASIA amendment publishes
- 2012 December 19th – FDAISA comment period closes
- **2013 UDI Final Rule and *draft* GUDID Guidance**

AMERİKA - FDA

T.C. Sağlık Bakanlığı
İlaç ve Tıbbi Cihaz Kurumu

FEDERAL REGISTER
The Daily Journal of the United States Government

Unique Device Identification System

A Rule by the Food and Drug Administration on 09/24/2013

ACTION Final Rule.

UDI sistemi, tıbbi cihazlar ile ilgili olumuz olaylarda bilgiye ulaşım kalitesini artırmada; FDA' in problemleri daha hızlı tanımlaması ve çözümlemesi adına oldukça büyük bir öneme sahip olacaktır.

FDA

UDI

Unique Device Identification

UDI (Unique Device Identification Number) Nedir?

T.C. Sağlık Bakanlığı
İlaç ve Tıbbi Cihaz Kurumu

UDI Unique Device Identification- Tekil Cihaz Kimliği

- numerik veya alphanumerik kodlama

Device identifier (DI) – Cihaz Tanımlayıcı Kısım

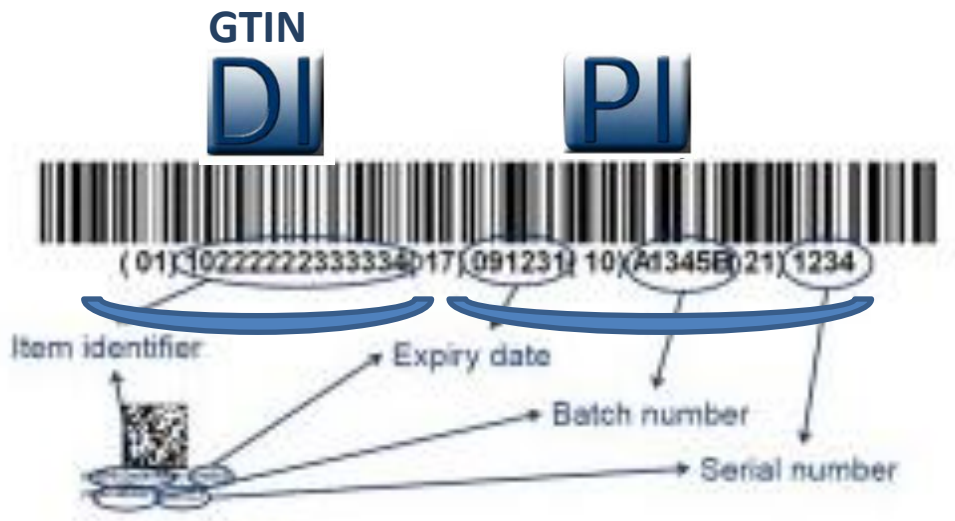
DI

Statik kısım
Üretici no ,cihaz modeli, referans no, GTIN

Production identifier(PI) – Üretim Tanımlayıcı Kısım

PI

Lot no.
Seri no.
Son kullanım tarihi
Üretim tarihi



DI + PI =UDI

FDA TARAFINDAN İLAN EDİLEN AJANSLAR

Health Industry Business Communications Council

GS1

HIBCC

ICCBBA

HIBCC's Labeler Identification Code (HIBC-LIC) is an alphanumeric code of up to 18 characters, and has been used historically in the medical device supply chain.

ISBT 128 is the International Standard for Blood and Transplant organs and can contain up to 128 characters.

Kan Torbaları

UDI Compliance Using GTINs

Both linear or 2D barcodes can be used for compliance with the UDI automatic ID identification requirement.

There are two ways use linear barcodes:

1. Use one linear with GTIN (DI) and Production Identifier (AI)
2. Use 2 separate barcodes, one for GTIN (DI) and one for Production Identifier (AI)

The third illustration here shows using the 2D barcode to combine all the data into one barcode.

GS1-128 "Concatenated" data

GS1-128 "Non-Concatenated" data

GS1 DataMatrix

(01)10857674002017
(17)141120
(10)1234AB

4.3.1 HIBC LIC Primary Data Structure

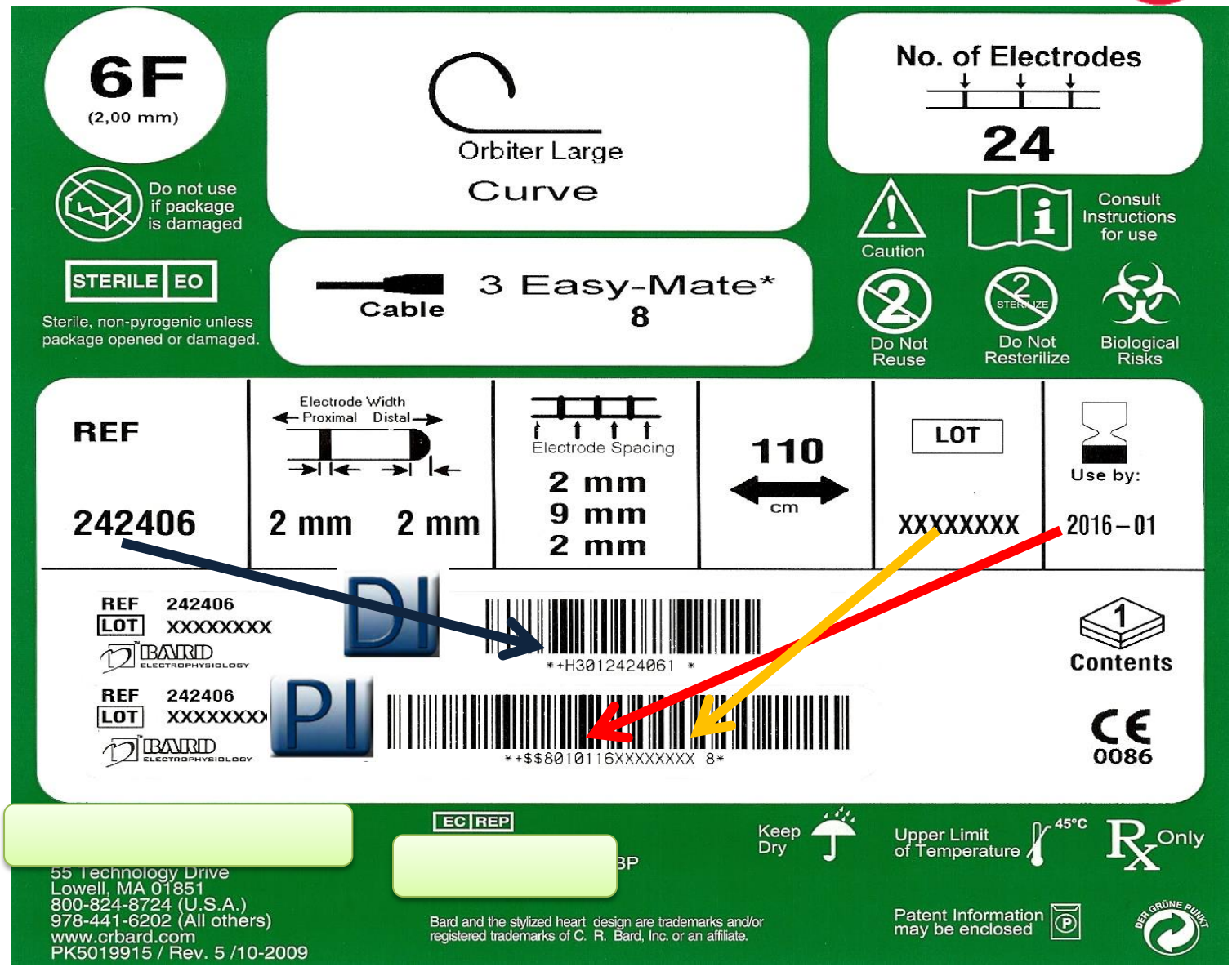
+A123BJC5D6E71G

4.3.3 HIBC LIC Concatenated Primary and Secondary Data in a 2D Symbol

*+A99912345/
$$59901510X3J*

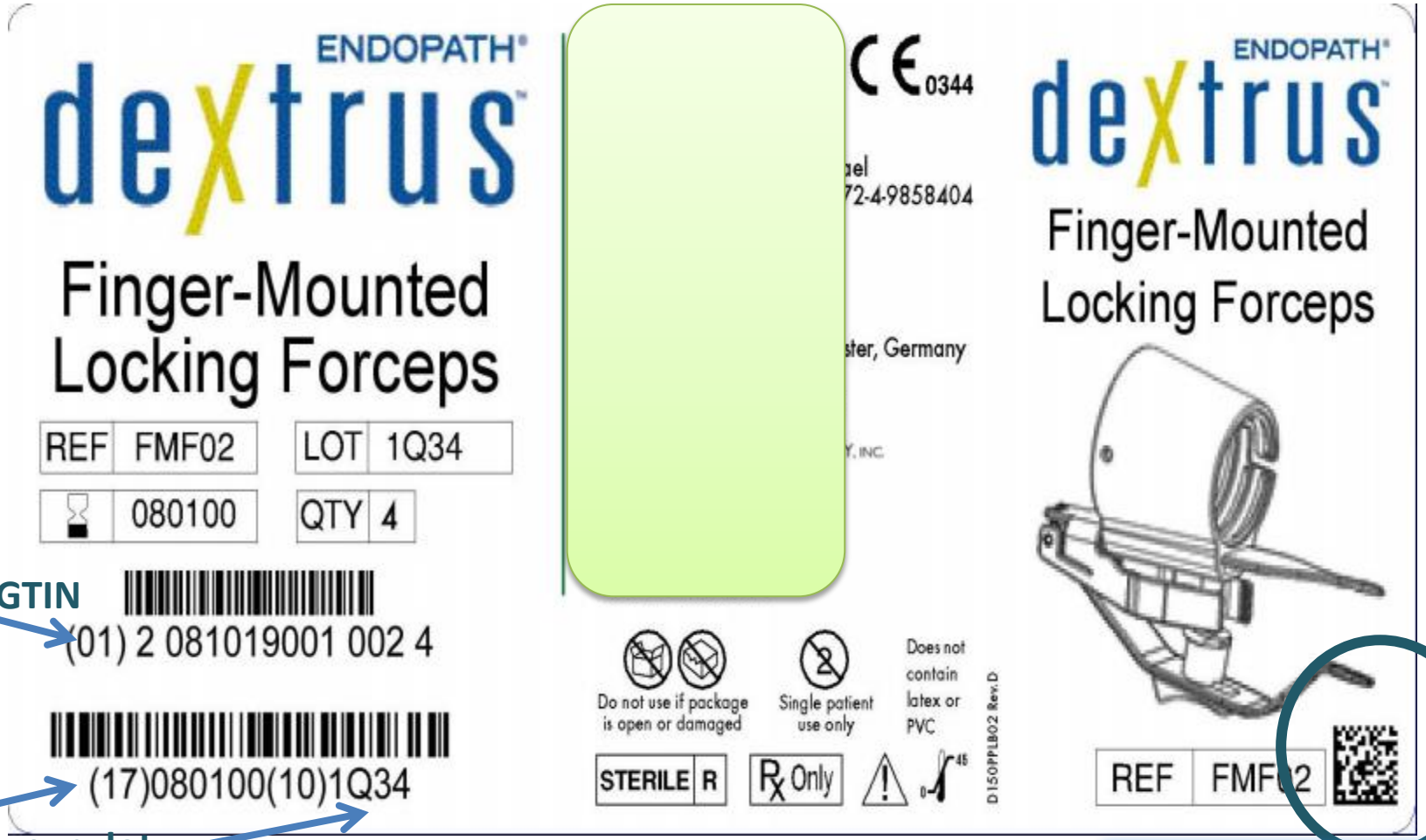
+ EXP DATE
+ LOT/BATCH
+ SERIAL NUMBER

UDI - Etiket Örnekleri



UDI - Etiket Örnekleri

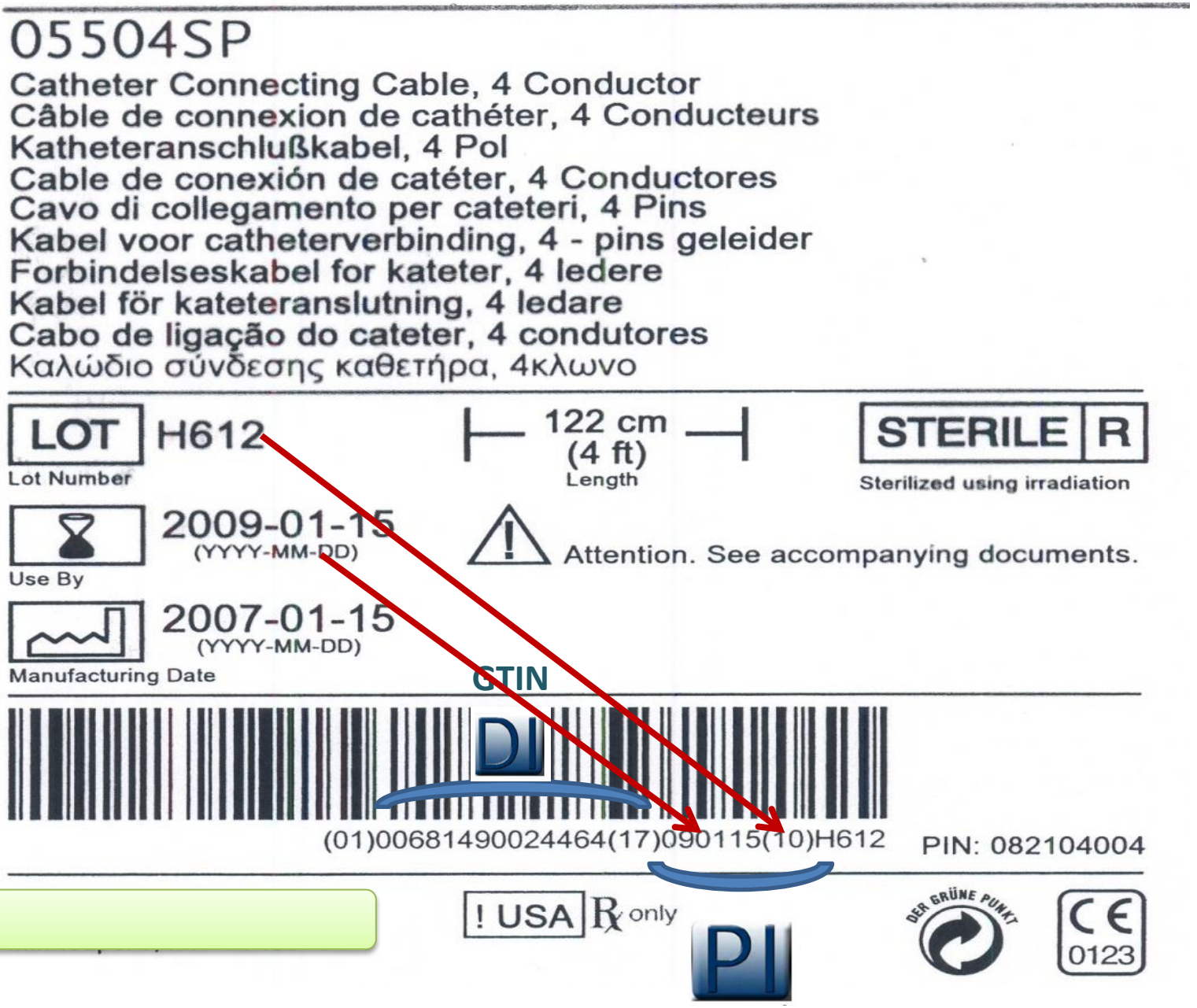
T.C. Sağlık Bakanlığı
İlaç ve Tıbbi Cihaz Kurumu



DI - GTIN

PI – exp, lot

DI + PI =UDI


05504SP
Catheter Connecting Cable, 4 Conductor
Câble de connexion de cathéter, 4 Conducteurs
Katheteranschlußkabel, 4 Pol
Cable de conexión de catéter, 4 Conductores
Cavo di collegamento per cateteri, 4 Pins
Kabel voor catheterverbinding, 4 - pins geleider
Forbindelseskabel for kateter, 4 ledere
Kabel för kateteranslutning, 4 ledare
Cabo de ligação do cateter, 4 condutores
Καλώδιο σύνδεσης καθετήρα, 4κλωνο
LOT H612
Lot Number
122 cm
(4 ft)
Length
STERILE R
Sterilized using irradiation
2009-01-15
(YYYY-MM-DD)
Use By
Attention. See accompanying documents.
2007-01-15
(YYYY-MM-DD)
Manufacturing Date
GTIN
DI
(01)00681490024464(17)090115(10)H612
PIN: 082104004
! USA Rx only
PI
DER GRÜNE PUNKT
CE
0123

RECOMMENDATIONS

COMMISSION RECOMMENDATION
of 5 April 2013
on a common framework for a unique device identification system of medical devices in the Union
(Text with EEA relevance)
(2013/172/EU)

UDI sisteminin temel amacı hasta güvenliğini iyileştirmektir, bunun yanında;

1. Uyarı sistemi kapsamındaki geri çekme ve düzeltici faaliyetlerin etkin olarak yürütülmesi,
2. Pazar sonrası faaliyetler hakkında yetkili otoriteler arasında daha hızlı veri alışverişi sağlamak
3. Sahtecilik ve kaçakçılık ile mücadele,
4. Dağıtım kanalının kontrolü,
5. Stok kontrolü,
6. Geri ödeme ile ilgili politika belirleme

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 5 April 2013

on a common framework for a unique device identification system of medical devices in the Union

(Text with EEA relevance)

(2013/172/EU)

Süreç içerisinde, üye ülkeler kendi takip ve izleme sistemlerini oluşturmaya karar verirlerse, oluşturulacak sistem Avrupa Birliği'nde kullanılacak UDI ile uyumlu olmalıdır. Aksi hale oluşturulacak farklı sistemler karışıklığa yol açacak, ortak bir terminoloji sağlanamadığı gibi pazar denetimini kolaylaştırmak adına da hiçbir katkı sağlamayacaktır.

Contains Nonbinding Recommendations

Global Unique Device Identification Database (GUDID)

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 27, 2014.

The draft of this document was issued on September 24, 2013.

This document supersedes Global Unique Device Identification Database (GUDID), June 11, 2014.

Ulusal UDI Veritabanı Elemanları

T.C. Sağlık Bakanlığı
İlaç ve Tıbbi Cihaz Kurumu

ANNEX

DATA ELEMENTS OF THE NATIONAL UDI DATABASES

National databases on UDI should include the following data elements:

(a) quantity per package configuration;

(b) if applicable, alternative or additional identifier(s);

(c) the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number);

(d) if applicable, the unit of use device identifier (when a UDI is not assigned to the device at the level of its unit of use, a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient);

(e) name and address of the manufacturer (as indicated on the label);

(f) if applicable, name and address of the authorised representative (as indicated on the label);

(g) Global Medical Device Nomenclature (GMDN) code or internationally recognised nomenclature code;

(h) if applicable, trade/brand name;

Ulusal UDI Veritabanı Elemanları

T.C. Sağlık Bakanlığı
İlaç ve Tıbbi Cihaz Kurumu

ANNEX

DATA ELEMENTS OF THE NATIONAL UDI DATABASES

(h) if applicable, trade/brand name;

(i) if applicable, device model, reference, or catalogue number;

(j) if applicable, clinical size (including volume, length, gauge and diameter);

(k) additional product description (optional);

(l) if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use);

(m) if applicable, additional trade names of the device;

(n) labelled as single use device (y/n);

(o) if applicable, restricted number of reuses;

Ulusal UDI Veritabanı Elemanları

T.C. Sağlık Bakanlığı
İlaç ve Tıbbi Cihaz Kurumu

ANNEX

DATA ELEMENTS OF THE NATIONAL UDI DATABASES

(p) device packaged sterile (y/n);

(q) need for sterilisation before use (y/n);

(r) labelled as containing latex (y/n);

(s) labelled as containing DEPH (y/n

(t) URL for additional information, e.g. electronic instructions for use (optional);

(u) if applicable, critical warnings or contraindications.

UDI Takvimi

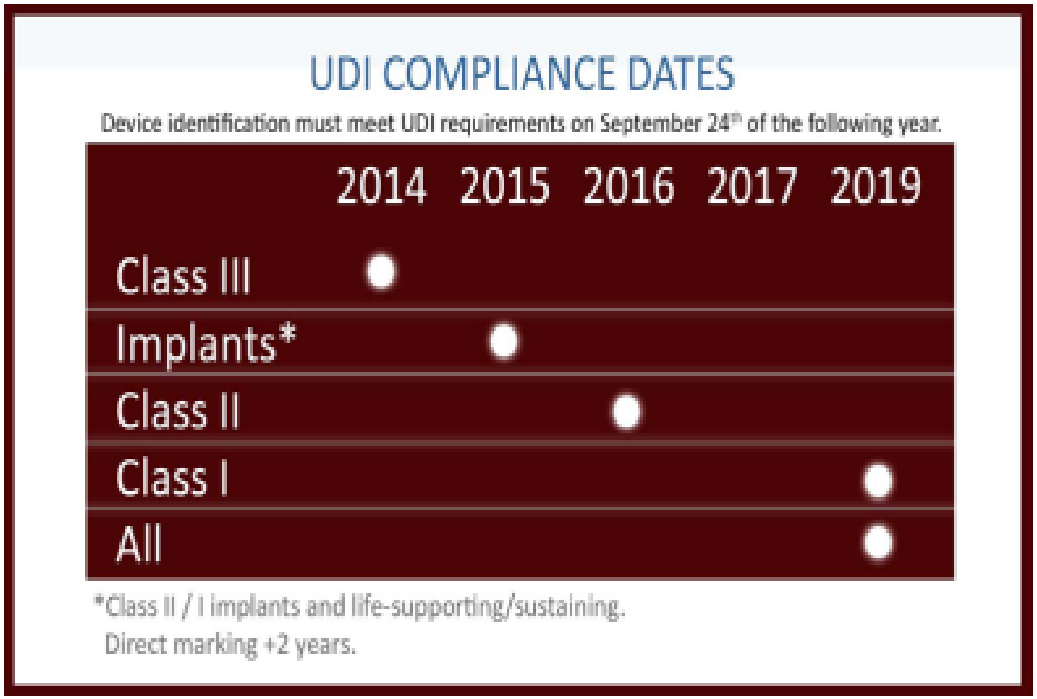
- 21 CFR 801.20
  - …the label of every medical device shall bear a unique device identifier (UDI)…

4. **RISK BASED APPROACH**

23. Should Member States intend to establish a UDI system they should follow a risk based approach in accordance with the classification of the device.

24. The UDI system should be implemented gradually, starting from highest risk class devices which should be the first to respect the condition to bear the UDI.

- 21 CFR 830.300
  - …the labeler of a device must provide the information required … for each model or version required to bear a unique device identifier (UDI)…



Tıbbi Cihazlar Dairesi
Müh. Funda ÖZDİLER ÇOPUR
E-mail: funda.ozdiler@titck.gov.tr

T.C. Sağlık Bakanlığı

Teşekkürler