UNIQUE DEVICE IDENTIFICATION

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Structure of the presentation

I. Introduction

II. The GHTF Ad hoc Working Group

III. Future actions at the EC level

INTRODUCTION

- Where do we stand?
- What are we talking about?
- Why are we talking about UDI, now?
- What are we doing on this topic?

State of play regarding UDI at the EC level

- **At the moment Nothing**

- Has been developed

- Has been officially decided

ONE TYPE OF UDI SYSTEM

Manufacturers

Users of the database are using the UDI CODE (static part) as Access key

UDI CODE (Data carrier, i.e. barcode,two-dimentionnal, ...)

UDI DATABASE

Manufacturer
Allergen
Packaging level
Sterility ...

GLOBALLY ACCEPTED

DATA EXCHANGE PROCESS

Unique CODE established by application of international standards

Static information

Lot/batch #

Serial #

Expiration date #

Dynamic information

Other voluntary beneficial informations #

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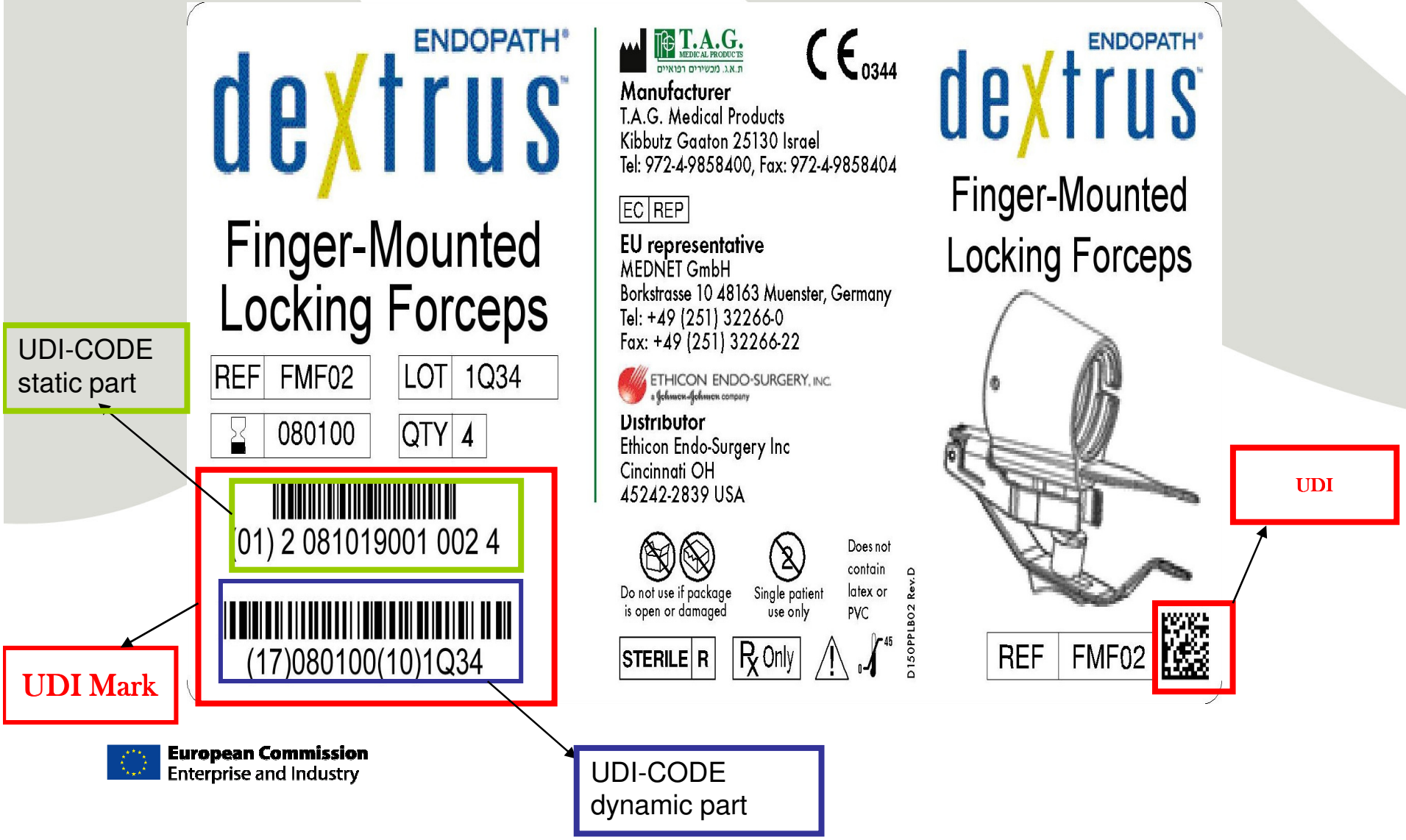
Example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UDI-CODE static part
UDI Mark
UDI-CODE dynamic part
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Why to act ?

- **<u>Mainly because developing a UDI will have positive consequences:</u>**
- Patient safety
- Market surveillance
- Data management for hospitals
- …

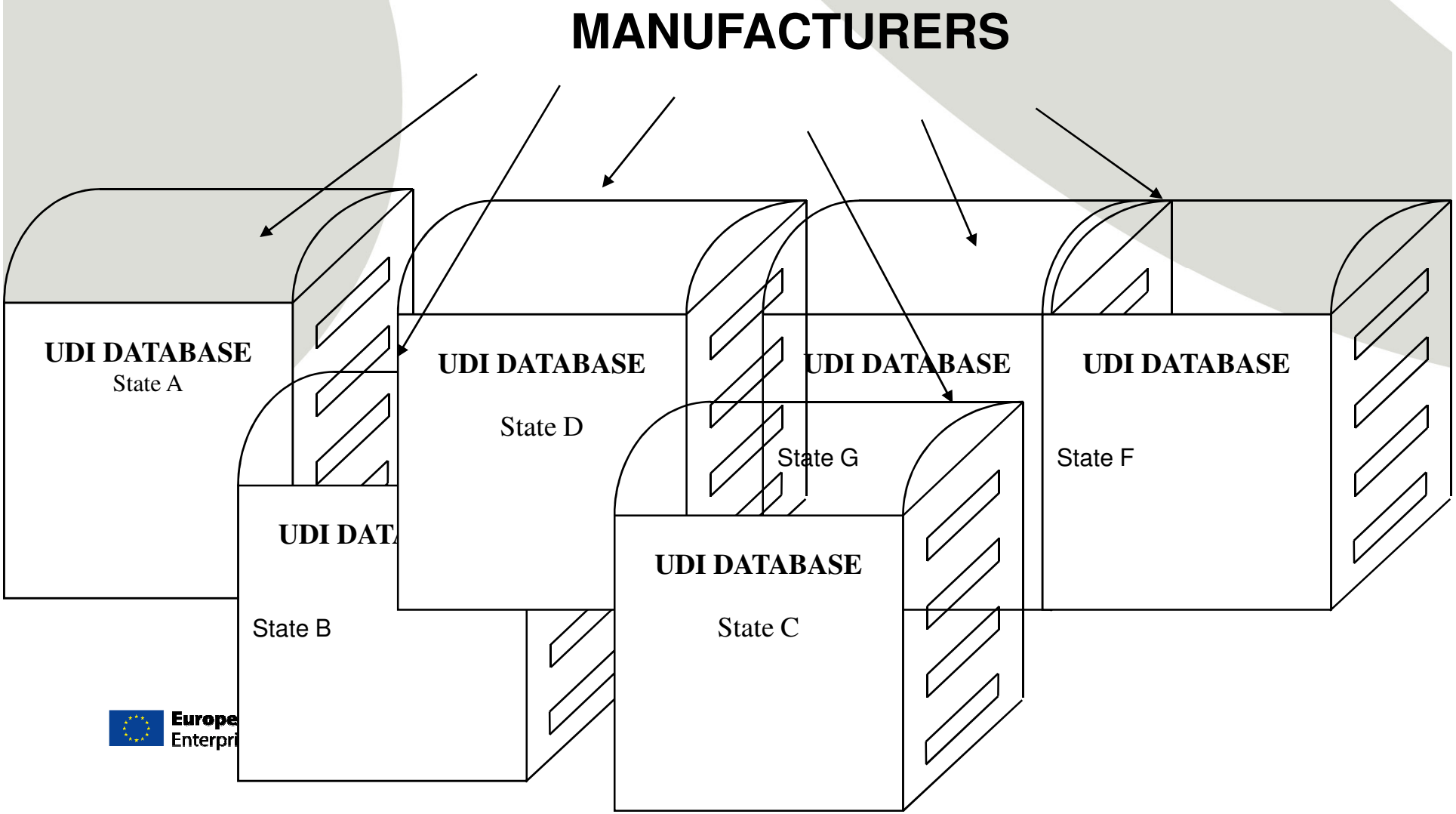
But why to act now ?

- The evolution of the technology

- The US is developing a UDI mechanism

And other States will follow

What is necessary to avoid



The US UDI work plan

- Adoption by the Congress: the 27th of September 2007
- The FDA is currently writing regulations
- Provisional timetable

Where to act?

- **<u>At the international level</u>**

GHTF – Global Harmonisation Task Force

- **<u>At the EC level</u>**

- Start reflexion
- Start brainstorming

II. WORK AT THE GHTF LEVEL

- The establishment of the Ad hoc WG
- The results achieved
- The results to come

The Ad hoc WG

- **The 8th of October 2008 establishment of an Ad hoc WG**

- Regulators / Industry

- US/Japan/Europe

Terms of reference (I)

- Establish co-operation with all stakeholders
- Insure global compatibility
- Define a minimum dataset needed for an effective global market surveillance

Terms of references (II)

- Address compatibility with the US FDA UDI mechanism and with other regional regulatory frameworks.

- Propose implementation of the UDI system into the GHTF-Model

Work achieved by the Ad hoc Working Group

- Two meetings took place

- The release of a questionnaire

ANALYSIS OF THE CURRENT OUTCOME

- A learning process
- The content of questionnaire

The discussion

- **<u>The most important thing is to confront</u>:**
- The different approaches

- The different definitions

The questionnaire

- Complex
- Lengthy

The questionnaire: 3 parts

- **First part**
  The label and the code on the product

- **Second part**
  Potential additional information to be provided by the manufacturer

- **Third part**
  The implementation of the UDI into the GHTF model

First part

- **AIDC (Automatic Identification and Data Capture) system**
- Type
- Standards
- Evolution

- **Coding system**
- Type of coding system
- Information readable with only the UDI

- **To which products UDI should be applied**
- All medical devices
- Different level of traceability

- **Privacy issues**

Second part

- Information to be provided by the manufacturer
- Standards for data exchange
- Management of the database

Third part

- Link with the GHTF-model
- Link with the GHTF guidance on medical device registration system

Next steps …

- Analysis of the answers
- Meetings to draw conclusions
- Developments of a general document to address the issue at the GHTF level
- Presentation of the work at the next GHTF conference in May 2009

III. THE WORK AT THE EUROPEAN LEVEL

- We are just starting
- We need to act
- How to act: the legislator dilemma
- Mainly opened questions

We are starting

- **The idea is**

- To avoid the multiplication of national systems at the EC level

- To develop an international approach

The dilemma of the legislator

- **FACTS:**

- It is a useful instrument

and

- then it will develop globally in the years to come

- **But** it cannot lead to an excessive increase of costs for producers

- **Therefore :**

Choices have to be made …

Balance

- **<u>A balance has to be found between:</u>**
- The potentialities of UDI

- The feasibility of UDI

Open questions …

- To which medical devices
- To which purposes
- Data protection issues
- Spare parts
- Parallel imports

Conclusion : Actions

- **Short term**
  The work of the GHTF Ad hoc WG
- **Medium term**
  Policy actions / Distribution channel studies
- **Long term**
  Recast

More info and contact:

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