

## UNIQUE DEVICE IDENTIFICATION

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### Introduction

Unique device identification (UDI) is the marking, labelling, tagging or otherwise identifying a device placed on the market.

EDMA has been made aware that in recent months various regulatory authorities have been considering the possibility of putting in place regulatory requirements for all medical devices, including in vitro diagnostics. Most recently the necessity of harmonization of the regulations on the use of UDI for medical devices has been discussed in the Global Harmonization Task Force.

This document states the position of the members of the European Diagnostic Manufacturers Association on the applicability of UDIs to in vitro diagnostics.

### Benefits of the UDI

The Unique device identification can be used for various purposes:

- **To improve patient safety by reducing device related medical errors, improving the identification of devices in adverse events, and facilitating field safety corrective actions.**
- To manage the purchase and the distribution
- To identify counterfeit devices

The criteria retained to develop a UDI system are dependent on the objective defined. This paper is focused on **the development of a UDI system to improve patient safety** which is today the consideration at the heart of discussions amongst stakeholders.

### Developing the UDI

It is worth noting that the higher the resolution of the traceability system, the more resources will be needed on the part of all the actors in the traceability chain – the users who may need to identify the devices and the authorities who will need to monitor the system.

The first consideration to take into account when developing a UDI system to improve patient safety is the risk of the device. It can be important to put in place such system for “high risk products”, but the system must be flexible to be efficient and certain categories of products should be exempted from UDI requirements.

For the products where it is necessary to improve patient safety, the UDI would be constructed by two elements:

- *Device Identifier:*  
Manufacturer reference and product reference
- *Production identifier:*  
“Serial number” if serialised, “lot number” if identified at the lot level

### Unit of Use

A question in developing a UDI system for device traceability is the resolution of the traceability system: i.e. whether a product should be traceable to the level of the individual “unit of use”. The key question is – does the increased resolution in traceability of the device provide an increase for patient safety?

This decision to request it or not should depend on the product, as for certain categories of devices, “lot number” ensures adequate patient safety.

## **Patient safety and UDI**

An essential part of a regulatory system in the medical field requires that a system of vigilance be in place to allow intervention in the market whenever a product is found to perform in a manner that puts the safety of patients at risk.

Intervention in the market is done by means of field safety corrective actions, which can range from advisory letters sent to the users of the concerned products, up to the withdrawal of the concerned products from the market.

It is therefore essential for the users, authorities and manufacturers to have a mechanism through which the concerned products can be traced and readily identified in order for field safety corrective actions to be effective.

Vigilance and traceability systems exist today. Keeping in mind the aim to improve patient safety, it is worthwhile looking in detail into the means by which product traceability is ensured today for IVD medical devices.

## **Considerations for IVDs**

In Vitro Diagnostics medical devices cover a range of devices – including laboratory analyzers, the reagents which are used to perform the assays on those analyzers, and self testing devices, such as those for pregnancy testing or glucose monitoring systems.

**Instruments** are identified by a unique serial number which serves as a UDI (this is a requirement of the harmonized standard EN 61010-2-101). IVD instruments therefore already include a UDI of the highest resolution (individual product identification).

**Reagents** are produced in homogeneous batches and then aliquoted or otherwise divided into smaller units for distribution. The unit of reagent which reaches the end user may be designed for single use (e.g. test strips), but most of the time allows

the end user to carry out several assays. Furthermore, for many diagnostic procedures several reagents are often needed. In these cases it is common practice to sell all of the reagents needed for a diagnostic procedure bundled in a diagnostic kit.

As a consequence of the production process, IVD reagents are identified by lot (or batch) number, as this represents a homogeneous unit of reagent. When reagents are sold within a kit, each individual reagent will bear its own lot number and the kit itself is also identified by a separate lot number.

**Therefore traceability for reagents is routinely established to the lot, rather than to the “unit of use”, which cannot be defined for most of IVD reagents.**

This level of traceability has been used in the EU since before the introduction of the IVD directive (98/79/EC) which establishes a regulatory requirement for the use of batch. These provisions have proven to be appropriate for fulfilling the traceability of devices with regards to field safety and corrective actions aimed to guarantee patient safety.

## **Specific UDI technologies**

There are a number of specific technologies which can be used to convey information on a device. These include writing, linear bar codes, data matrix bar codes, high capacity colour bar codes, radio frequency identifiers (RFID) etc.

All of these technologies serve the same function – to allow information to accompany a device. The question on the use of such technologies is separate from the level of resolution which is needed for traceability.

The use of specific UDI technologies should be standardized so that for a single device a single UDI should be required. What the specific technology for the device will be would be determined by the characteristics of the device.



The participation of manufacturers, authorities and healthcare professionals in standardization initiatives through GS1 Healthcare offers a unique forum of discussion to further develop existing standards or to create new standards if necessary.

### **EDMA Position on UDIs**

Unique Device Identification should serve to support the traceability of devices in order to ensure patient safety, as part of the market surveillance system. It can be important to put in place such system for “high risk medical devices”, but the system must be flexible in order to be efficient.

**A stepwise approach based on the level of risk should be envisaged.**

**Global harmonisation of the regulations on the use of UDI for Medical Devices is essential. Different UDI approaches adopted in a particular country or region should be avoided.**

In the case of in vitro diagnostic medical devices, the current practice is to serialise instruments and to use lot numbers to trace reagents, rather than directly to the “unit of use”, which cannot be defined for most of IVD reagents. EDMA believes that this level of traceability has been shown to be adequate and that there should not be more stringent regulatory requirements for in vitro diagnostic traceability.

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### **References:**

[EDMA Note to the EU Commission on UDI](#)

[FDA Policy page on UDI](#)

[Advanced Response to FDA consultation on UDI](#)

**The EDMA UDI Ad Hoc Group**