Eucomed
Medical Technology

POSITION PAPER
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# Risk-based approach for UDI marking requirements of medical devices at the various packaging levels

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# Introduction

The purpose of this paper is to provide guidance on how UDI marking can be implemented at the different packaging levels of medical devices using a risk-based approach. The GHTF UDI Guidance September 2011 *(www.ghtf.org/ahwg/ahwg-final.html)* promotes the use of a risk-based approach as part of the UDI implementation for marking requirements of device packaging. This approach has already established the UDI implementation sequence, starting with Class III (high risk) devices. This will allow the next phases; Class IIb, IIa & I, to benefit from the experience gained with Class III implementation.

*Note: throughout this document reference is made to the EU Device Classes III, IIb, IIa & I. The approximate US equivalents are Classes 3, 2 & 1.*

# Background and position

Below is an extract from the GHTF UDI Guidance document relating to this requirement:

1. *Introduction: Other issues that need to be considered for the successful development and implementation of a globally harmonized UDI System include:*
    - *A **risk-based approach** is essential given the huge diversity of the medical devices […]*
    - ***The requirements** should be phased in over a period of years based on premarket **risk class**, starting with the highest risk class first, to help to reduce the complexity of implementation*

5.8. *The national / regional regulation for UDI system shall include a robust process for evaluating and adjudicating applications for UDI exemptions that would exempt **certain device types or package levels (including direct part marking) from being labeled with UDI** or specific elements in the UDID.*

7.1. *The UDI Carrier (AIDC and HRI representation of the UDI) shall be on the label of the device, its package, or on the device itself, and on all higher levels of packaging.*

7.2. ***The UDI Carrier for low risk devices packaged and labeled individually does not need to be on its package but rather on a higher level of packaging**, e.g. carton. However, when the user is not expected to have access (e.g., home user) to the higher level of packaging (e.g., carton), the UDI should be on its package.*

The marking requirements for Class III (high risk) and Class I (low risk) devices have been precisely defined in the GHTF UDI Guidance. Nevertheless, the terminology *"low risk"* leaves room for

interpretation as to whether it could include Class IIa and/or IIb devices. This could create divergence in national regulations and adversely impact global harmonization. In addition, manufacturers have already set, or are currently setting out, their implementation strategy based upon their own interpretation of current GHTF UDI Guidance, existing regulations and customer requirements. These projects are being implemented 'now' and given that such changes need to be introduced a long time in advance of the device being available on the market, it is therefore relevant to establish a commonly understood risk-based approach at an early stage for ensuring consistent implementation by the manufacturers.

The IMDRF *(International Medical Device Regulators Forum)* UDI Working Group is now setting up the principles and roadmap of UDI implementation. It is essential that this group develops further guidance and defines the UDI marking requirements, at the various packaging levels, depending on the device risk class, specifically for Class IIa/b devices. The vast majority of the devices placed on the market belong to these risk classes (representing more than 50% of the devices on the market), therefore the guidance is essential for consistent harmonised global UDI implementation.

Eucomed is supportive of the risk-based approach (as previously advised in its 2009 position paper) as part of UDI implementation. The updated table below is based upon an extract from a previous Eucomed response to the GHTF UDI ad hoc work group (March 2010). It summarises the proposed marking requirements at the different packaging levels based upon device classification. This proposal is explained further, for each risk class, below the table.

| | **Unit Pack**(1) | | **Shelf / Sales Carton** |
|---|---|---|---|
| | Mandatory | Optional(2) | Mandatory |
| **Class**(5) **I / 1** | | Device Identifier (DI)(3) | Device Identifier + Production Identifier |
| **Class IIa, IIb / 2** | Device Identifier | Production Identifier (PI)(4) | Device Identifier + Production Identifier |
| **Class III / 3** | Device Identifier + Production Identifier | | Device Identifier + Production Identifier |

Note:

(1) Technical feasibility prerequisite (space, substrate etc.).
*Unit Pack - the immediate package around an Individual Unit of Use or, in some cases, Multiple Units of Use.*

(2) At the manufacturer's discretion (e.g. for internal processes), but not to be used for regulatory purposes

(3) Does not exclude the use of a Production Identifier, which is at the manufacturer's discretion

(4) Production Identifier = Expiry Date + Lot Number or Serial Number
*It is at the manufacturer's decision whether the device is 'Lot Number' or 'Serial Number' controlled*

(5) EU - Class I/IIa/IIb/III – USA - Class 1/2/3

## Class I devices

The above proposal for Class I devices is in alignment with GHTF UDI Guidance:

> *"The UDI Carrier for low risk devices packaged and labelled individually does not need to be on its package but rather on a higher level of packaging, e.g. shelf pack or carton."*

UDI shall be marked at the shelf/sales carton level with marking of the unit pack left to the discretion of the manufacturer.

## Class IIa and IIb devices

These classes of device are typically produced in high volumes (mass-produced) and are generally considered as low cost consumable items (syringes, needles, catheters...) with many of these devices being for single use or single patient use. Higher packaging levels (shelf/sales carton) need UDI marking, including both Device Identifier (DI) and Production Identifier (PI).

For the unit pack level, several points need to be considered when establishing marking requirements:

- The use of UDI by healthcare providers at the unit pack level (or on the device itself - direct part marking) needs to be further assessed. The feedback collected to date, from healthcare providers for this class of device, shows that unit pack UDI marking is not yet used at the patient's bedside. Bedside scanning for this class of device (low value - high consumption) would require huge involvement for healthcare providers (e.g. technical equipment, IT infrastructure, additional work steps). This involvement is the key for understanding the needs for UDI marking requirements. Eucomed therefore strongly recommends involving healthcare providers in the IMDRF discussions for establishing the relevant marking requirements on the unit pack for Class IIa/b devices.

- Although the Device Identifier can be pre-printed on packaging/labelling, at the unit pack level in an AIDC format, the UDI marking to include 'variable' Production Identifiers in this format, requires a more complex on-line printing capability beyond that currently used for the regulated variable information in a human readable format. In this case the usage of a pre-printed UDI is no longer possible and printing technology, applications and equipment would probably need to be installed or upgraded and qualified on every packaging line. Such complex printing is considered as the main driver of efforts from the manufacturer's side.

Considering the above points, Eucomed recommends that UDI coding for the Production Identifier, at the unit pack level, should not be a mandatory requirement for Class IIa/b devices. Nevertheless the device identifier component of the UDI should be included in an AIDC format at this level (when technically feasible, e.g. no space constraints) to allow for the positive identification of the device by the user, if needed. It would also make the link with the UDI Database (UDID) which holds the required device data elements (attributes). The Production Identifiers (Lot/Batch and expiry date), even if not a component of the AIDC marking at the unit pack level, would still be available in a human readable format, as required by regulation.

## Class III devices

Using the Device Identifier and the Production Identifiers at all packaging levels (when technically feasible), as recommended in the GHTF UDI Guidance, is fully justified. The requirements are well understood and accepted for this device class.

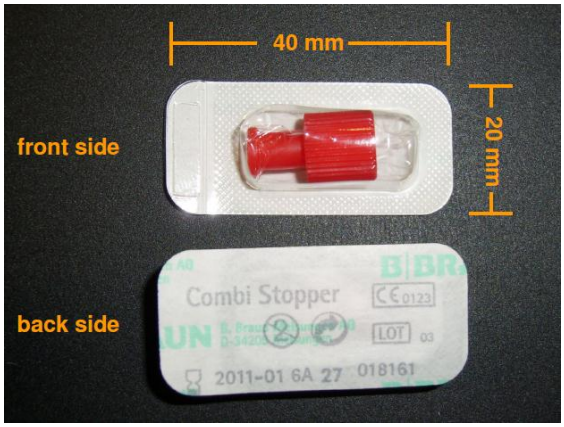
# Conclusion

For both Class IIa/b and Class III devices, it is important that the IMDRF UDI Working Group precisely define the technical feasibility and pre-requisites for UDI marking (Class III devices) or partial UDI marking (only Device Identifier for Class IIa/b devices) at the unit pack level. The unit pack can have very limited space which has to include mandatory information as required by the existing regulations from different regions, e.g. information required by the Medical Device Directive 93/42/EEC and by regulations in force in other regions. As the packaging is often designed to serve several markets/regions, multilingual information adds to the space limitation for including additional requirements such as UDI. For some devices this will result in no flexibility for adding UDI marking, even if considering 2D marking technology. The examples provided in the Annex illustrate the various sizes of labels and packs and the complexity for including UDI. This specific constraint for the unit pack needs to be considered as part of the technical feasibility criteria for UDI implementation.

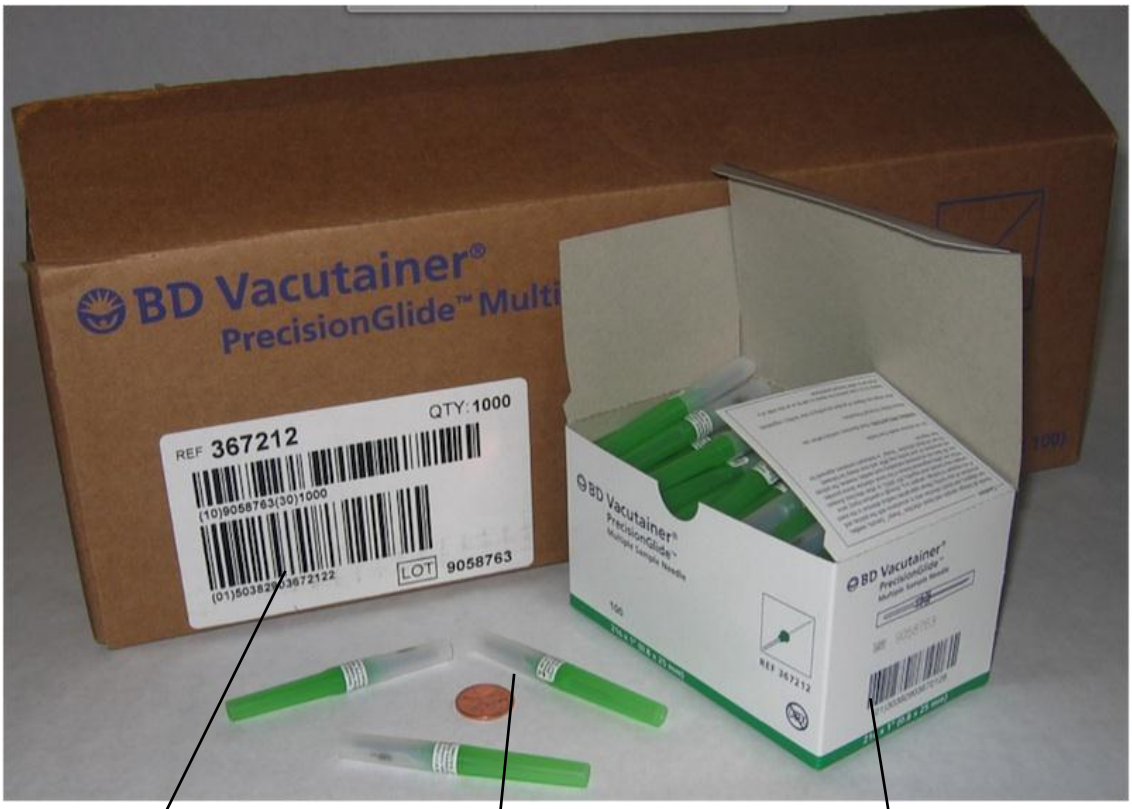
# Annex



Variable print area




Examples of small device label/packaging for which Device Identifier (AIDC) cannot be added.

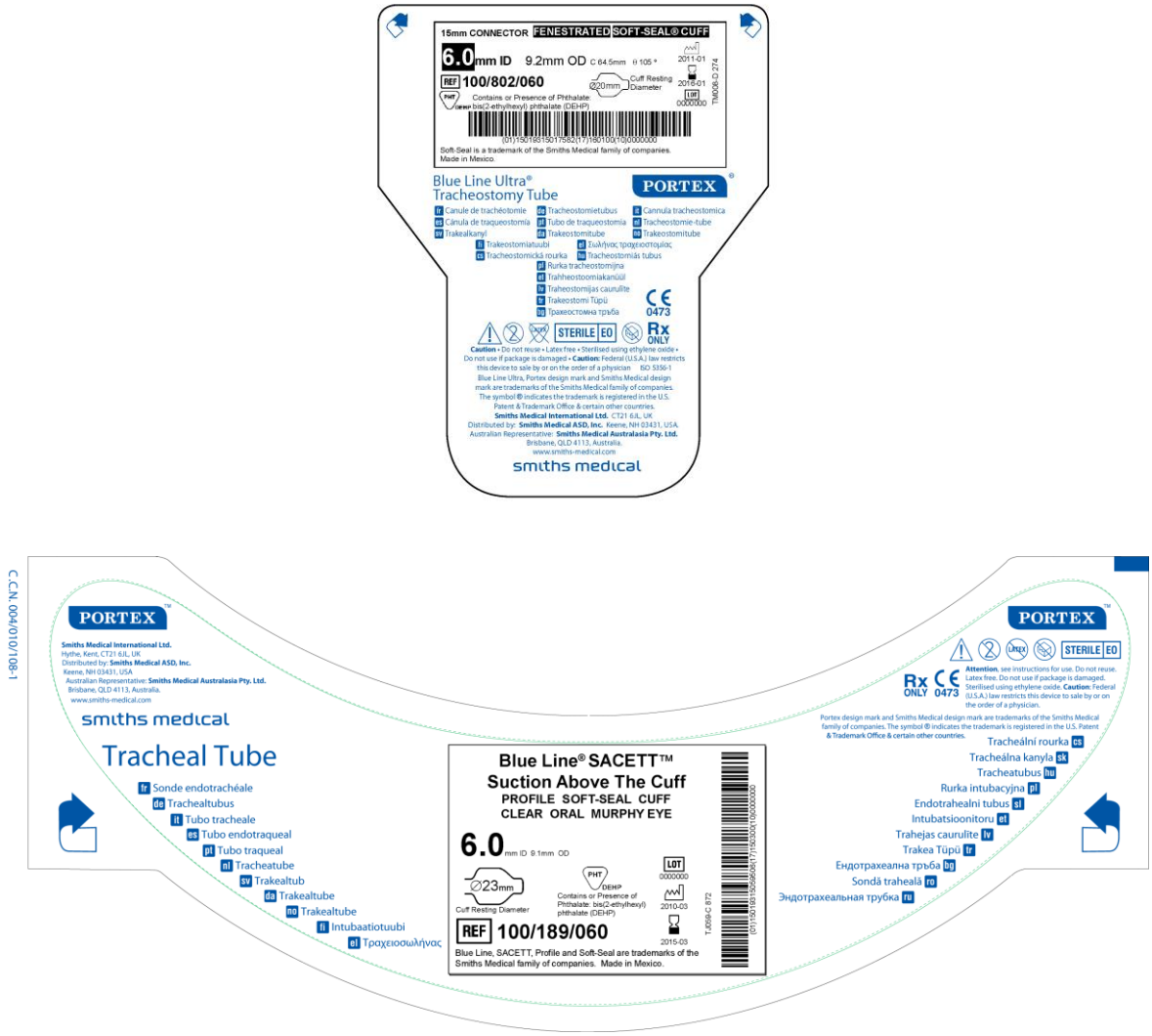



Shipping carton: including DI and PI in AIDC format

Unit label: in this example there is not enough space to include UDI in AIDC format

Shelf box: Including DI and PI in AIDC format

Example of different packaging levels and proposed coding (this example is a US device)




Examples of ‘medium size’ Class IIa multilingual unit packs with UDI and human readable information

# About Eucomed

Eucomed represents the medical technology industry in Europe. Our mission is to make modern, innovative and reliable medical technology available to more people.

Eucomed members include both national and pan-European trade and product associations as well as medical technology manufacturers. We represent designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability.

The industry we represent employs more than 500,000 highly skilled workers, turns over €95 billion per year, invests some €7.5 billion in R&D and encompasses of approximately 500,000 different medical technologies from sticking plasters and wheel chairs through to pacemakers and replacement joints.

Eucomed promotes a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of society.

For more information:

Merlin Rietschel
Manager Regulatory & Technical Affairs
E: merlin.rietschel@eucomed.org
T: +32 (0)2 775 92 23
Visit www.eucomed.org