Summary & Guidelines for New FDA Unique Device Identification Requirements

As a result of the FDAs' final ruling on medical devices Unique Device Identification (UDI) System final ruling in September 2013, and its' follow-up Global Unique Device Identity Database (GUDID) Guidance document published more recently in June 2014, this publication has been prepared in order to simplify and assist in understanding the compliance requirements necessary in order to achieve regulatory acceptance. The UDI system has been implemented by the FDA in order to stratify and simplify the traceability of all classes of medical devices manufactured and distributed in the United States, alongside certain products registered under the Public Health Services (PHS) Act that incorporate medical devices. The outcomes of the final ruling are expected to:

- Improve the quality of information which is recorded on medical devices and medical device packaging.
- Standardize the data that is presented on the label
- Simplify data analysis of medical device within data recording systems
- Assist in prevention of counterfeiting
- Facilitate rapid regulatory action following the occurrence of Adverse Event Reports (AER's) in medical devices
- Assist in rapid, specific and targeted product recalls
- Reduce medical errors and improve patient safety
- Lead a global directive in medical device identification

The UDI label must be applied to the medical device (as primary packaging) and secondary packaging. The FDA ruling dictates that UDI must be must be provided in a 'plain text version and in a form that uses automatic identification and data capture (AICD) technology'. Stipulations are that is must consist of two specific and discreet aspects:

1. *A device identifier (DI):* This is **mandatory** and must identify the **Labeller** and **specific model/version** of the device

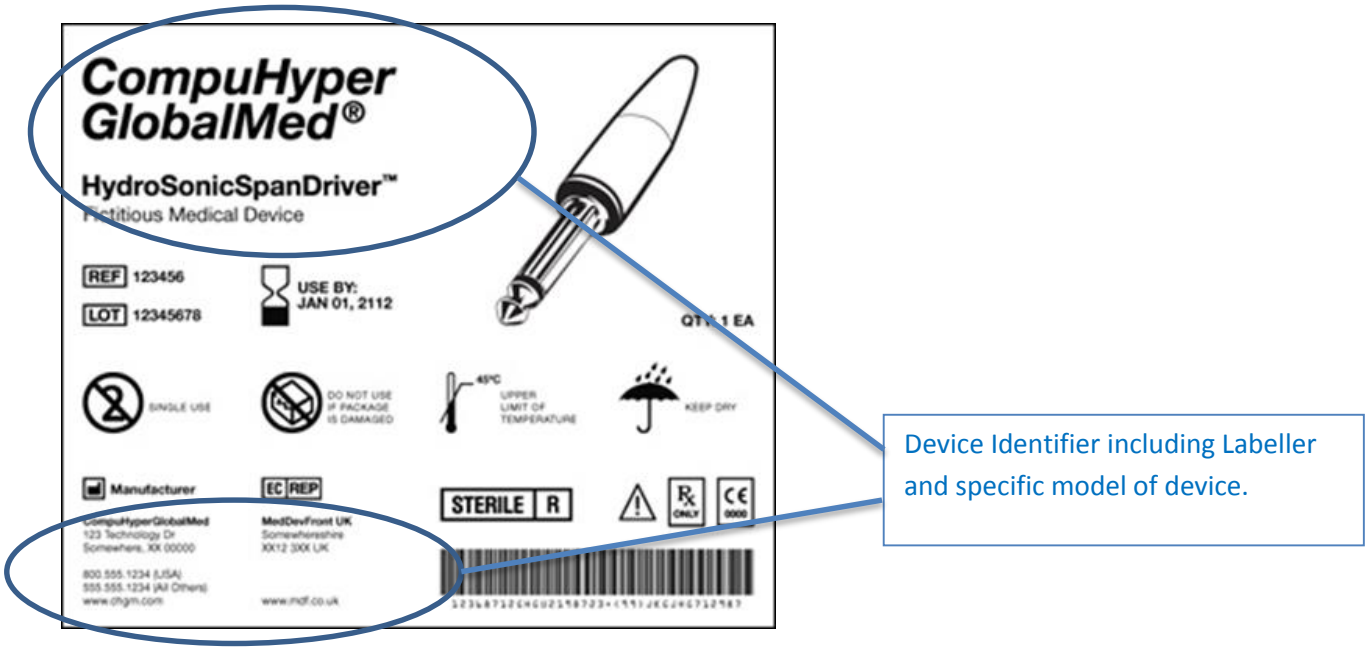

Fig 1: Fictitious example 1 of a medical device UID label illustrating DI as proposed by the FDA

2. *A product identifier (PI):* This is **conditional and variable** depending on the device, must include one or more of the following:
    - Lot or batch number within which a device was manufactured
    - Serial number of the specific device
    - Expiry date of the specific device
    - Date of manufacture
    - Distinct Identification Code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based products (HCT/P) regulated as a medical device.

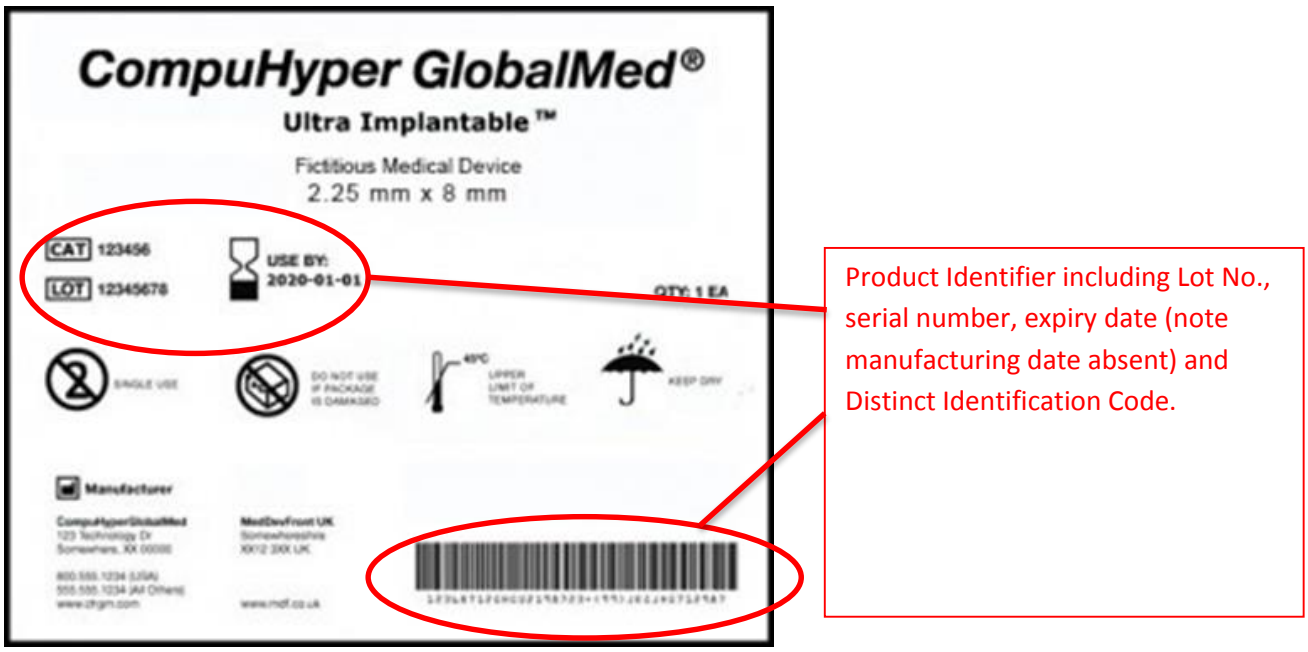

Fig 2: Fictitious example of a medical device UID label illustrating Product Identifier as proposed by the FDA

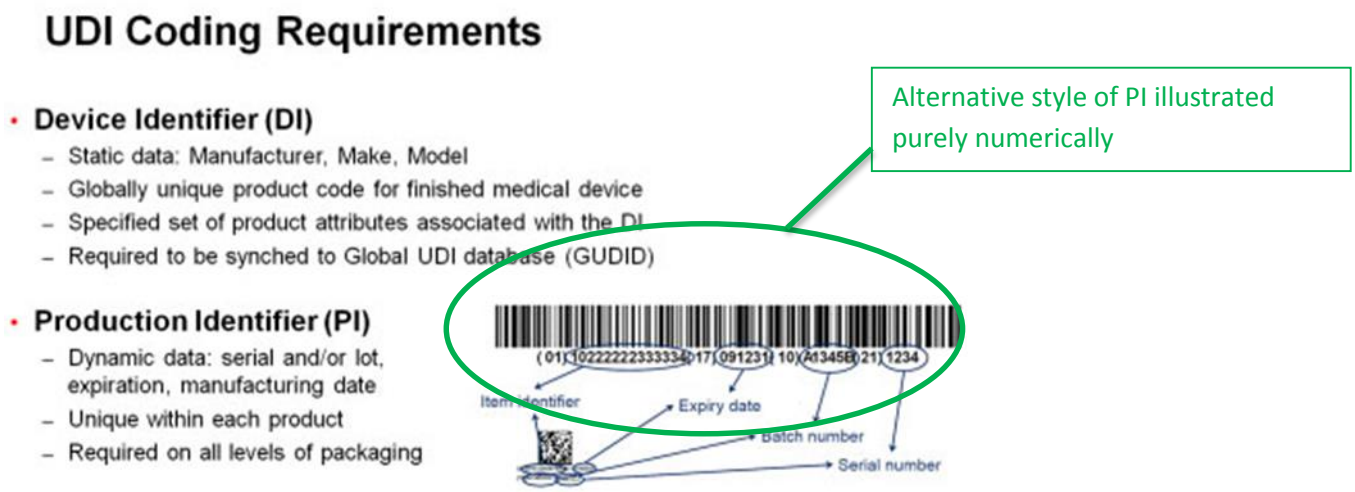

Fig 3: Alternative example of UDI illustrating DI and PI requirements in order to comply with new FDA UDI regulations

Included in the FDA ruling is the stipulation that each device supporting a UDI must be recorded on the newly constructed Global Unique Device Identification Database (GUDID). The GUDID is intended to be a central depository for traceable information for all supplied medical devices of all classes within the United States. The data provided for the GUDID will be available to the general public and should include only the DI. Submission of the PI is not required. Furthermore although the general public will be able to request and see information relating to specific devices, no personal user information will be held on the GUDID.

UDI & GUDID Implementation Dates:

The implementation programme as outlined by the FDA is set to roll out over the next 7 years to progressively incorporate all classes of medical devices for UDI application and GUDID information submission. Initially targeting Class III devices it is set to progress as follows:

Class III Devices:

Date:	Requirements:
Sept 2014	All labels and packaging of devices must incorporate a UDI Dates on labels must be formatted as stipulated Data must be submitted to the GUDID database 1 year-extension for compliance must be applied for by 23rd June 2014 Stand-alone Class III software must provide its' UDI as required
Sept 2016	Any Class III device intended for use more than once must bear a permanent marking UDI

Life Supporting/Life Sustaining Devices:

Date:	Requirements:
Sept 2015	All labels and packaging of devices must incorporate a UDI Dates on labels must be formatted as stipulated Data must be submitted to the GUDID database Stand-alone software for these devices must provide its' UDI as required Any Life Supporting/Life Sustaining device intended for use more than once must bear a permanent marking UDI

Class II Medical Devices

Date:	Requirements:
Sept 2016	All labels and packaging of devices must incorporate a UDI Dates on labels must be formatted as stipulated Data must be submitted to the GUDID database Stand-alone Class II software must provide its' UDI as required
Sept 2018	Any Class II device intended for use more than once must bear a permanent marking UDI

Class I Medical Devices and other Devices Not Classified as Class I, II or III

Date:	Requirements:
Sept 2018	All labels and packaging of ALL devices (including those previously exempt) must incorporate a UDI Dates on labels of ALL devices (including those previously exempt) must be formatted as stipulated Data for ALL devices (including those previously exempt) must be submitted to the GUDID database Stand-alone Class I software must provide its' UDI as required
Sept 2020	Any Class I device or and device that has not been classified into Class I, II, or 3 but requires labelling with a UDI, which is intended for use more than once must bear a permanent marking UDI

UDI Exceptions:

The UDI rule does allow for exceptions of for the requirements of § 801.20 for certain categories of medical devices. It is possible to request an exemption or alternative for UDI marking if either an acceptable alternative method of identification is used, or if the exception is viewed as being in the best interest of public health. Application and assessment for this process takes place directly through the FDA.

Accrediting Agencies:

The FDA has currently allocated 3 agencies with accreditation to assign UDI's outlined below:

1. Firm Name: GS1
   Website: www.gs1.org
2. Firm Name: Health Industry Business Communications Council (HIBCC)
   Website: www.hibcc.org
3. Firm Name: ICCBBA
   Website: www.iccbba.org

Relevant Links:

http://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf

https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIExceptionsAlternativesandTimeExtensions/default.htm