

**Quick Reference Guide & Checklist for FDA Regulatory UDI Requirements § 801.20:**

As outlined by the FDA the following are the requirements for UDI medical device labelling of all classes of medical device (requirement as of September 2013).

**Device Identifier:**

Content:	Completed:
Labeller information	
Specific model/version information	

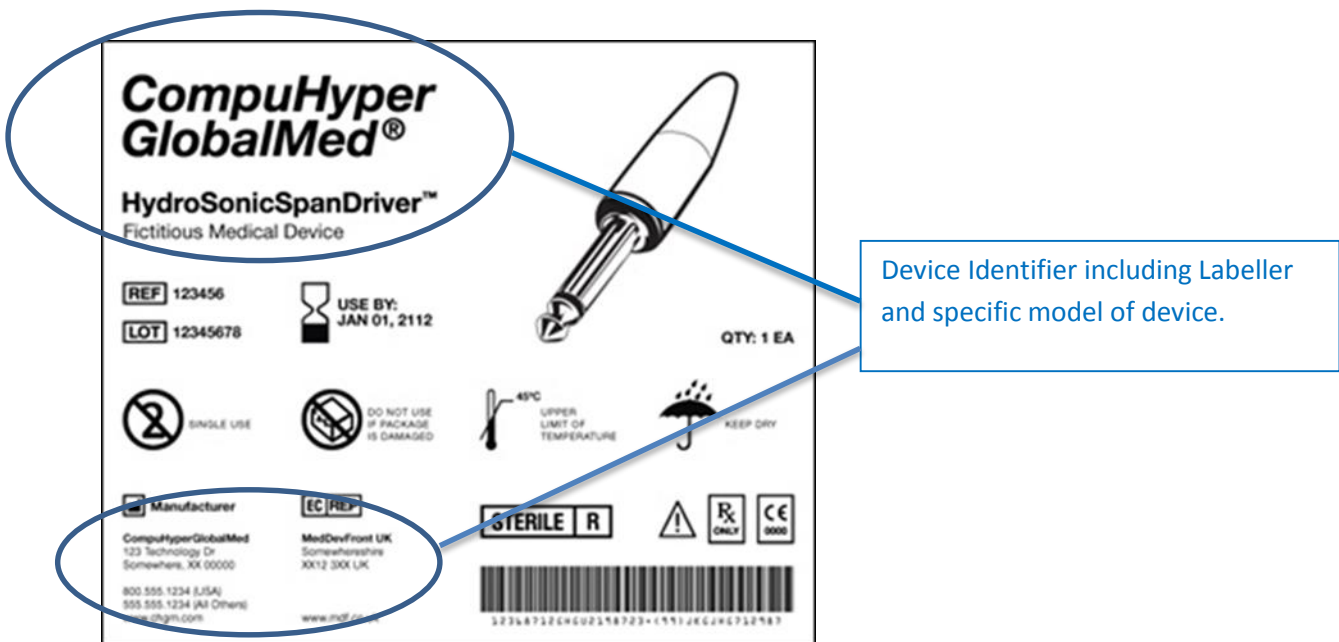


Fig 1: Fictitious example 1 of a medical device UID label illustrating DI as proposed by the FDA:

**Product Identifier:**

Content:	Completed:
Lot or batch number within which a device was manufactured	
Serial number of specific device	
Expiry date of specific device	
Date of manufacture	
Distinct Identification Code as required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based products (HCT/P) regulated as a medical device	

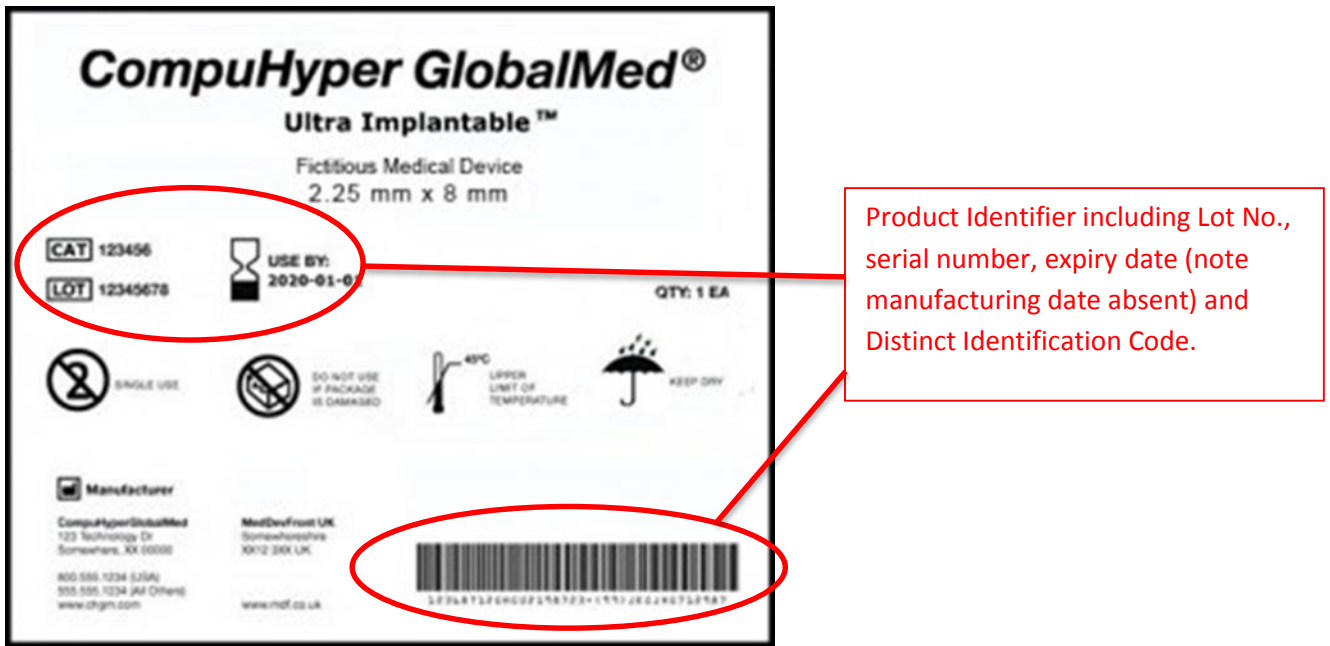


Fig 2: Fictitious example of a medical device UID label illustrating Product Identifier as proposed by the FDA

## UDI Coding Requirements

- **Device Identifier (DI)**
  - Static data: Manufacturer, Make, Model
  - Globally unique product code for finished medical device
  - Specified set of product attributes associated with the DI
  - Required to be synched to Global UDI database (GUDID)
- **Production Identifier (PI)**
  - Dynamic data: serial and/or lot, expiration, manufacturing date
  - Unique within each product
  - Required on all levels of packaging

Alternative style of PI illustrated purely numerically



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

### GUDID Submission:

Medical device:	Accrediting Agency:	Submission Date