



455 Boleskine Road
Victoria BC, Canada
V8Z 1E7

T 1.250.388.3537
F 1.250.483.1975

starfishmedical.com

StarFish Analysis: UDI Compliance date, 24 September 2016, fast approaching

By Virginia Anastassova, 7 June 2016

Do you have class II devices in your portfolio? If you do, chances are that you need to comply with the FDA requirements for Unique Device Identifiers. The deadline for class II devices is fast approaching on September 24, 2016.

The list of tasks associated with implementing the UDI requirements is quite long and this could be a lengthy undertaking:

- Identifying devices that need UDIs
- Deciding if you are going to manage and maintain UDI in house or hire a consulting company
- Choosing a bar code standard and an accredited issuing agency
- Identifying the data needed
- Listing your devices on [GUDID](#)
- Making sure your labels have space to accommodate a UDI
- Ordering new labels (consider lead time)

Even if you only have one product, it is a good idea to be ready in advance of the September 24, 2016 deadline and avoid the last minute rush.

You can find the UDI compliance dates and useful information on the FDA [website](#).