



Health Industry Business
Communications Council



Getting Starting: HIBCC's Guide to UDI Compliance

Step 1: Register with HIBCC to get your Labeler Identification Code (LIC), which is a required part of UDI. You can download the form by visiting the HIBCC website at <https://www.hibcc.org/udi-labeling-standards/apply-for-a-lic/>

Step 2: Download the HIBC Supplier Labeling Standard 2.6 as a guiding document to creating your HIBC bar codes and UDIs. You can download the standard at http://www.hibcc.org/wp-content/uploads/ANS_HIBC_SLS_2.6_2016.pdf

Step 3: Request a Global UDI Database (GUDID) account for your company from the FDA. You can fill out the form on the FDA website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416113.htm>

Step 4: Obtain the necessary software to create bar codes for your product IDs in conformance with the HIBC standards (see Step 2). You can also create sample bar codes and UDIs on the HIBCC website at these links <http://www.hibcc.org/udi-labeling-standards/create-a-bar-code/>

Step 5: Download the HIBCC UDI Decoder App and scan the HIBCC Auto-ID symbols you created in Step 4. The application will identify the various components of the UDI that you will submit to the FDA's GUDID. The HIBCC UDI Decoder App is available, free of charge, for both Android and Apple iOS smartphone and tablet platforms. Download the app from the Google Play and Apple App stores by searching "HIBCC UDI Decoder".
<https://play.google.com/store/apps/>
<https://itunes.apple.com/us/app>

Step 6: Submit your UDI Device Identifiers to the FDA's GUDID using one of the FDA's submission options; GUDID web interface or HL7 SPL submission. To learn more about the two submission options visit the FDA website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/default.htm>