**Health Industry Business
Communications Council**

HIBCC

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
https://www.hibcc.org/wp-content/uploads/SLS-2.6-Final.pdf

Step 3: 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 this link
https://hibccudi.org/

*Step 4 (USA): Request a Global UDI Database (GUDID) account for your company from the FDA. You can fill out the form on the FDA website at
https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/request-gudid-account

* For EU MDR/IVDR UDI compliance skip to Step 6.

Step 5 (USA): 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

Step 6 (EU): Generate Basic UDI-DIs for groups of similar devices by following the HIBCC guidance and entering your data at the link https://www.hibcc.org/basic-udi-di-generator/

Step 7 (EU): Complete the EUDAMED Actor Registration process and obtain an SRN for your organization at https://webgate.ec.europa.eu/eudamed/landing-page#/