UDI: Implementation and Application

September 18, 2019

Presented to MTAA Workshop

Presented by Robert A Hankin, PhD
President & CEO
HIBCC
US FDA UDI Final Rule passed September 2013

The UDI Rule was established to:

- Facilitate the rapid and accurate identification of all devices
- Improve the process for device recalls
- Standardize device labeling and identification for electronic health records, clinical information systems, claims data sources and registries
- Allow all stakeholders to access important device information
<table>
<thead>
<tr>
<th>Date</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 24, 2014</td>
<td>The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI.</td>
</tr>
<tr>
<td>September 24, 2015</td>
<td>The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI.</td>
</tr>
<tr>
<td>September 24, 2016</td>
<td>The labels and packages of class II medical devices must bear a UDI. A class III device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use.</td>
</tr>
<tr>
<td>September 24, 2018</td>
<td>A class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. The labels and packages of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI.</td>
</tr>
<tr>
<td>September 24, 2020</td>
<td>Class I devices, and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI, must a bear UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use.</td>
</tr>
<tr>
<td>Date</td>
<td>Requirement</td>
</tr>
<tr>
<td>--------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>September 24, 2020</strong></td>
<td>FDA does not intend to enforce UDI labeling, GUDID Data Submission, and Standard Date requirements for Class I and unclassified devices manufactured and labeled on or after September 24, 2018.</td>
</tr>
<tr>
<td><strong>September 24, 2021</strong></td>
<td>FDA does not intend to enforce UDI labeling, GUDID Data Submission, and Standard Date requirements for finished Class I and unclassified devices manufactured and labeled before September 24, 2018.</td>
</tr>
<tr>
<td><strong>September 24, 2022</strong></td>
<td>FDA does not intend to enforce Direct Mark requirements for Class I and unclassified devices.</td>
</tr>
</tbody>
</table>
What is an Issuing Agency?

US FDA accrediting three issuing agencies for the issuance of UDIs

- HIBCC, GS1, and ICCBBA
- Each issuing agency has an approved labeling standard
- All UDIs must be in one of the approved issuing agency formats
HIBCC: An FDA and EU Accredited Issuing Agency

Industry-supported, internationally accredited nonprofit SDO with an exclusive healthcare focus.

Identified by the European Union (EU) and the International Medical Device Forum (IMDRF) in their Medical Device Regulation (MDR)

Accredited by ANSI, CEN, and ISO.
HIBCC UDI Key Characteristics

Alphanumeric dataset means:
- Largest set of possible identifiers
- Literal encoding of existing product codes
- No cross referencing, no duplicates, and codes never need to be reused

Labeler Identification Code (LIC) registration is a one-time fee. There are no recurring or annual costs to use the HIBCC system.

Accepted globally.

One LIC can be used to create all your UDIs.

To complete the LIC application visit www.hibcc.org.
What is a UDI?

A UDI is composed of the Device Identifier (DI) and the Production Identifier (PI).

The DI is the mandatory, fixed portion of the UDI. A HIBCC DI includes the following:
- Labeler Identification Code (LIC) – Company Prefix assigned by HIBCC
- Product/Catalog Code
- Unit of Measure (Package level indicator)

The PI is the variable, conditional portion of the UDI. A HIBCC PI may include one or more of the following:
- Lot
- Serial
- Manufacture Date
- Expiration Date
The GUDID is a repository of device identification information

- Contains only the fixed Device Identifier (DI) portion of the UDI
- Contains other identification information specific to the device

Example:

- LIC = A999
- Product Code = ABC123
- Unit of Measure = 0 (single unit)
- DI that is entered in to the GUDID = A999ABC1230
Submitting to GUDID

Requesting a GUDID Account
➢ Complete GUDID request form on the FDA’s website

Step 1: Submit Your New GUDID Account Inquiry

1. Change your email’s filter settings to allow emails from GUDISupport@HHS.gov and helpdesk@salesforce.com so that you will receive future communications from the UDI Help Desk.
2. Submit the following information to initiate a GUDID New Account Inquiry:

<table>
<thead>
<tr>
<th>Field</th>
<th>Information Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>First Name</td>
</tr>
<tr>
<td>Last Name</td>
<td>Last Name</td>
</tr>
<tr>
<td>Organization</td>
<td>Organization</td>
</tr>
<tr>
<td>Email</td>
<td>Email</td>
</tr>
<tr>
<td>Phone</td>
<td>Phone</td>
</tr>
</tbody>
</table>

Submit
Submitting to GUDID

Receive automated email with GUDID PDF application form ➢ Follow the instructions shown on the FDA UDI website

Step 2: Complete the GUDID New Account Request

After you submit the GUDID New Account inquiry, the FDA UDI Help Desk will email you the GUDID New Account Request document in a fillable PDF format.

If you do not receive an immediate reply in your inbox, check your spam or junk folder. If the email was sent to your spam or junk folder, adjust your email filters as noted in Step 1.

1. Open the GUDID New Account Request document in Adobe Acrobat.
2. Complete all fields in the document and save the PDF file.
3. Reply to the FDA UDI Help Desk email with the completed PDF attached. A UDI Help Desk analyst will review your request and respond as soon as possible.

For all technical questions relating to setting up or accessing your GUDID account, please contact the FDA UDI Help Desk.
Submitting to GUDID

Required Information for completing the GUDID New Account Request Application

- Organization DUNS Number
- One Valid FDA Premarket Number (either PMA or 510k)
  - If 510k exempt, you will need to submit an FDA Listing Number instead
  - 510k can be provided by manufacturer
- Device Identifier Prefix from an FDA-accredited Issuing Agency
  - Labeler Identification Code (LIC), Company Prefix, or Facility Identification Code (FIN)
Submitting to GUDID

FDA Global Unique Device Identification Database (GUDID) New Account Request

Labeled Organization Information
Organization ID/Number represents the labeler’s view of the highest corporate level in the labeled organization; it may be the DUNS number for headquarters, or the parent DUNS for the labeler included in the GUDID account. Please ensure that the name and address in the DUNS database are accurate because the GUDID will pull the organization name and address from the DUNS database.

Organization DUNS Number: 
Organization Name: 
Address: 

Regulatory Contact Information:
Individual responsible for GUDID submission requirements for the labeler included in this GUDID account request.
First Name: 
Last Name: 
Email Address: 
Phone Number: 
Alternative Phone Number: 
Physical Address: 

Are you a Third Party Regulatory Contact? 

Yes
No

FDA Premarket Number
Please provide one valid FDA Premarket Number (PMA, 510k, etc.) for a device currently marketed in the U.S. 

FDA Premarket Application Number: 
If 510k exempt, check here and provide the FDA Listing Number instead: 

Device Identifier Prefix
Work with an FDA-accredited issuing Agency to obtain a prefix (Company Prefix, Labeler Identification Code (LIC), or Facility Identification Number (FIN) that will be used to construct your Device Identifiers.
Prefixes that will be used to construct your Device Identifiers:

1 Data Universal Numbering System or D-U-N-S Number is a unique nine-digit identification number assigned and managed by Dun & Bradstreet (D&B) to business entities. For more information, visit http://www.dnb.com/products_services/dnbstructure/productlist.aspx

2 DUNS Regulatory Contact, confidence and accuracy of entry and information made available to the public.

Page 1 and 2 are REQUIRED to be filled out completely. Page 3 is required only if applicable.
This is for new account requests ONLY. For changes to existing GUDID accounts, please contact the FDA UDI Help Desk, www.fda.gov/ud"
Types of GUDID Accounts

Web Interface (Production Only)
- Use this option to manually enter individual records
- Should be used for organizations with low number of records
- No testing period for Web Interface accounts

HL7 SPL Pre-production
- Use this option to electronically upload multiple records at a time
- Testing is required – Allow several weeks for testing and approval

HL7 SPL Production
- Once testing is approved through your HL7 SPL Pre-production account, you will be able to apply for the Production account
- Must submit FDA GUDID Case # assigned during testing phase
Types of GUDID Accounts

<table>
<thead>
<tr>
<th>FDA Global Unique Device Identification Database (GUDID) New Account Request</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indicate GUDID Submission Options</strong></td>
</tr>
<tr>
<td>□ Web Interface Production ONLY</td>
</tr>
<tr>
<td>□ HL7 SPL Pre-production: Testing is required before an HL7 SPL Production account will be granted.</td>
</tr>
<tr>
<td>Are you a Third Party requesting a GUDID test account?</td>
</tr>
<tr>
<td>□ Yes   □ No</td>
</tr>
<tr>
<td>□ HL7 SPL Production: Testing completed and verified in FDA UDI Help Desk case #</td>
</tr>
</tbody>
</table>
Preparing for GUDID Record Submissions

Review FDA GUDID Data Elements Reference Table
➢ Table provides all fields in the GUDID (mandatory, optional, conditional)
➢ Contact Issuing Agency for questions on Device Identifier portion of submission
➢ Review Access GUDID to view current public records in the GUDID
GUDID Device Identifiers

Primary Device Identifier
- The Primary DI is the DI located on the lowest package level that contains a UDI.

Unit of Use Device Identifier
- A Unit of Use DI is required to be entered in the GUDID when the Primary DI contains more than one device and those devices are not individually labeled with a UDI.

Package Device Identifier
- A device identifier for the package configuration that contains multiple units of the base package.
The GUDID has many additional data elements (required and conditional) to be completed by the labeler

- Production Identifiers
- Device Characteristics
- Device Classification
  - GMDN Code or FDA Preferred Term Code
  - Premarket Submission Number or 510k
  - FDA Product Code
  - FDA Listing Number
Types of GUDID Account Logins

Coordinator
- This account login is automatically provided to the contact on the GUDID New Account Application Form
- Coordinators can review all records created
- Coordinators can not submit new records

Labeler Data Entry User
- This account login can be created through the “Manage Account” function when logged in as a Coordinator
- Must be logged in as a Labeler Data Entry User to create new records
- An Individual can have both a Coordinator and a Labeler Data Entry User accounts
Creating Labeler Data Entry
User Account Login
Creating Labeler Data Entry
User Account Login
Each GUDID Device record must have a GMDN or FDA Preferred Term Code

The GMDN Agency is responsible for the Global Medical Device Nomenclature (GMDN) used to identify medical devices.

- Must be a member to obtain GMDN
- As of April 1, 2019 GMDN offers free Basic membership

FDA Preferred Term Code are assigned to each GMDN term used in place of a GMDN Code.

- Searchable by device description through your GUDID account
- Enables labelers to submit GUDID records prior to obtaining a GMDN code from the GMDN Agency
FDA Preferred Term Code Search Function
FDA Preferred Term Code Search Function
What if a GMDN Term Code Does not Exist for my Device?

Contact GMDN to have a term code created
- Must be a GMDN Member

Select GMDN Code or FDA Preferred Term Code that best fits device description

Kits and Combination Devices
- Select the code with the closest description to device
- May submit multiple codes
Common GUDID Questions

Who is the labeler?
➢ Manufacturer, Distributor, Re-labeler

What is included in a single device identifier record?
➢ Primary DI, Unit of Use DI, Direct Marking DI, Package DI

What constitutes a separate device identifier record?
➢ Variations of a device, kits, combination products
Maintaining GUDID Compliance

When do I need to create a new device identifier record?
- Brand new device
- New variation or version of an existing device
- Re-branding or acquisition of a device

When do I need to update an existing device identifier record?
- Updated GMDN or FDA Preferred Term Code
- New packaging configuration
- Commercial distribution end date
GUDID Data Quality Issues

Device Identifier Errors
- Typos/Transpositions – Most Common
- Lack of understanding of DI Field

Multiple Records
- Duplicate records of the same device
- Multiple DIs for the same device
Common Points of Confusion

Do I need a UDI prior to applying for a 510k?
 No, you do not need a UDI prior to the 510k. You will need a valid 510k prior to submitting to the GUDID.

How do I know if my GUDID record is approved?
 There is no approval process for GUDID records. There are certain validations embedded in the record (i.e. length of characters in a certain field).

Why do I not see my record in Access GUDID (Public Interface)?
 There is a 7 day grace period for records submitted to the GUDID. During the grace period, the record remains private and fully editable.
How do I create barcodes?

- Most organizations purchase barcoding software (i.e. BarTender, LabelView, Nice Label, Easy Label, etc.). HIBCC also has a UDI/barcode generator available on our website.
FDA UDI Exceptions

General Exceptions

- Class I devices are not required to include a production Identifier (PI)
- Shipping containers are exempt from the UDI Rule
- Devices manufactured and labeled prior to the compliance date remain valid for 3 years after the compliance date.
- Individual Single-Use devices distributed together and intended to be stored in the same device package until use, do not need to be individually labeled with a UDI.
- Custom devices (as defined by FDA) are exempt

Requesting an Exception

- FDA will evaluate additional exceptions on a case-by-case basis
- The labeler must explain why the labeling requirement is not technologically feasible.
FDA UDI Extensions

Extensions Granted
- Soft contact lenses – One year after FDA develops a technical solution for DI submissions of contact lenses
- Repackaged Single-Use Devices – September 24, 2018
- Rigid Gas Permeable Contact Lenses – September 24, 2017
- Single-Use, sterilized implants – September 24, 2016
Two new Regulations (Regulation (EU) 745/2017 on medical devices and Regulation (EU) 746/2017 on In Vitro diagnostic medical devices) were adopted in April 2017 and entered into force on 25 May 2017.

These Regulations introduce an EU identification system for medical devices based on a Unique Device Identifier (UDI).

The UDI system will facilitate easier traceability of medical devices, significantly enhance the effectiveness of the post-market safety-related activities for devices and allow for better monitoring by competent authorities. It will also help to reduce medical errors and to fight against falsified devices.
## EU MDR Compliance Dates

<table>
<thead>
<tr>
<th>Date</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 26, 2020</td>
<td>End of transitional period. Date that regulation will apply fully. Devices with existing certificates are valid until May 27, 2024.</td>
</tr>
<tr>
<td>May 26, 2021</td>
<td>Implantable and Class III device labeling deadline</td>
</tr>
<tr>
<td>May 26, 2023</td>
<td>Class IIa and Class IIb device labeling deadline</td>
</tr>
<tr>
<td></td>
<td>Direct marking of reusable implantable and Class III device deadline</td>
</tr>
<tr>
<td>May 27, 2024</td>
<td>Maximum validity of existing certificates</td>
</tr>
<tr>
<td>May 26, 2025</td>
<td>Class I device labeling deadline</td>
</tr>
<tr>
<td></td>
<td>Direct marking of reusable Class IIa and Class IIb device deadline</td>
</tr>
<tr>
<td></td>
<td>Any devices not in compliance in the supply chain that have not reached the end user are no longer marketable and must be withdrawn.</td>
</tr>
<tr>
<td>May 27, 2027</td>
<td>Direct marking of reusable Class I device deadline</td>
</tr>
</tbody>
</table>

*Note: Eudamed requirements may have an additional 18-month transitional period*
The European Commission has accredited four issuing agencies for the issuance of UDIs:

- HIBCC, GS1, ICCBBA, and IFA GmbH (geared towards pharmaceuticals)
- Each issuing agency has an approved labeling standard
- All UDIs must be in one of the approved issuing agency formats
EU Basic UDI-DI

The EU Basic UDI-DI is the main access key for device-related information in the EUDAMED database and it is referenced in relevant documentation [e.g. certificates (including certificate of free sale), EU declaration of conformity, technical documentation and summary of safety and (clinical) performance)].

It is intended to identify and connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics.

It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item.

Any Basic UDI-DI shall identify the devices (group) covered by that Basic UDI-DI in a unique manner.
### HIBCC Solution for EU Basic UDI DI

<table>
<thead>
<tr>
<th>Field Length</th>
<th>Format</th>
<th>Example</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>++</td>
<td>2 Fixed Length</td>
<td>++</td>
<td>HIBC Basic UDI-DI Flag Character “++”</td>
</tr>
<tr>
<td>Labeler Identification Code</td>
<td>4 Fixed Length Alphanumeric</td>
<td>A999</td>
<td>Labeler Identification Code (LIC) an alphanumeric identifier, with the first character always being alphabetic.</td>
</tr>
<tr>
<td>Model Identifier</td>
<td>1-17 Variable Length Alphanumeric</td>
<td>MODELIDENTIFIER11</td>
<td>Identifier assigned by the LIC-holder to represent devices with the same intended purpose, risk class, and essential design and manufacturing characteristics</td>
</tr>
<tr>
<td>Check Character</td>
<td>2 Fixed Length Alphanumeric</td>
<td>TK</td>
<td>Calculated using Mod 1021 and Mod 32</td>
</tr>
</tbody>
</table>

**Example:**

```
++A999MODELIDENTIFIER11S8
```
Key Differences Between US FDA UDI and EU UDI

Rules for Exemption
- EU - If there are significant restraints to include both AIDC and HRI, only the AIDC is required
- US - Must be in both AIDC and HRI, with exceptions

Direct Marking
- EU - If there are significant restraints to include both AIDC and HRI, only the AIDC is required
- US – Either the AIDC or HRI is required, not both

Single Use Devices
- EU – Devices should be packaged and labeled individually
- US – Single use devices stored in the same package do not need to be individually labeled
Key Differences Between US FDA UDI and EU UDI

Manufacture Date
- EU - The manufacture date is not required to be included in the UDI-PI, even if it appears on the label. If there are no other PI fields, then the manufacture date may be included in the PI.
- US - The manufacture date must be included in the PI, if it appears on the label

Software
- EU - Software delivered on a physical medium must have a UDI that is identical to the UDI assigned at the system level.
- US - Software delivered in packaged and not packaged form may have the same UDI, but it is not a requirement.

Base Package
- EU – UDI-DI identifies an individual device
- US – Primary DI is the lowest level of a medical device package containing a full UDI
Key Differences Between US FDA UDI and EU UDI

Responsibility of UDI Assignment and Data Entry
- EU – Manufacturer
- US – Labeler

Changes to Data Already Submitted
- EU – Within 30 days of a change being made, which does not require a new UDI-DI
- US - Updated information must be submitted no later than the date a device is first labelled with the changed information. If the information does not appear on the label of a device, the updated information must be submitted within 10 business days of the change

Implantable Device UDI
- EU - The UDI of the implantable device shall be identifiable prior to implantation
- US - No similar requirement called out in the US regulation
HIBCC UDI Services

Globally Accredited Labeling Standards

UDI & Labeling Technical Support

Sample HIBC UDIs & Bar Codes Can Be Created Directly On Our Website

Label & Bar Code Review Upon Request

Software Vendor Recommendations & Referrals

Downloadable HIBCC UDI Decoder Mobile App

For more information on HIBCC and UDI visit www.hibcc.org. To contact HIBCC directly email info@hibcc.org or call (602) 381-1091.
Questions?

For more information on HIBCC and UDI visit www.hibcc.org or www.hibcc.eu. To contact HIBCC directly email info@hibcc.org or udisupport@hibcc.eu or call +1 (602) 381-1091.