UDI: Implementation and Application

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Presented to CIMDR

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US FDA UDI Rule

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*

US FDA UDI Rule: Compliance Dates

Date	Requirement
September 24, 2014	The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI.
September 24, 2015	The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI.
September 24, 2016	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.
September 24, 2018	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.
September 24 , 2020	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.

US FDA UDI Rule: Compliance Dates Enforcement Discretion

Date	Requirement
September 24, 2020	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.
September 24, 2021	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.
September 24, 2022	FDA does not intend to enforce Direct Mark requirements for Class I and unclassified devices.

EU Medical Device Regulation (MDR) Background

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

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devices not in compliance in the supply chain that have not reached the end user are no longer marketable and must be withdrawn.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

*Note: Eudamed requirements may have an additional 18-month transitional period

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*

Key Differences Between US FDA UDI and EU UDI

Minimal differences in labeling requirements. Majority of differences are in exceptions and database requirements.

- *Basic UDI – DI (EU MDR only, virtual identifier)*
- *Existing inventory exemptions (2025 for EU MDR / 3 years post UDI implementation date for US FDA)*
- *Location/form of UDI carrier on labeling of small packages (Only AIDC required for EU MDR / Both AIDC and HRI required, with exceptions, for US FDA)*

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*

EU MDR Issuing Agencies

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*

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.

ANSI American National Standards Institute

ISO International Organization for Standardization

cen European Committee for Standardization
Comité Européen de Normalisation
Europäisches Kommitee für Normung

Common Myths Dispelled

Myth: Everyone should adopt a single bar code standard

- *There are no regulatory agencies that require a single standard for UDI compliance*
- *Scanners can read any bar code, regardless of standard*

Myth: HIBCC is only in the US

- *The HIBC standard is accepted globally*
- *HIBCC has labelers across the world (View list of labelers)*

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.

Choosing an Issuing Agency

HIBCC

- *Alphanumeric*
- *Variable Length Product Codes*
- *Healthcare Specific Products*
- *One-time Fee*

GS1

- *Numeric Only*
- *Fixed Length Product Code*
- *Retail Products*
- *Annual Fees*

HIBCC UDI Suite

HIBCC UDI Suite – Create UDI

Primary Data Structure

Step One Enter Your Data

The LIC registered address should match your FDA GUDID account information. If not, you can use our Apply for or Update an LIC.

Registered Company Name	CH BIOMEDICAL, INC.
Division/Subsidiary Name	
Registered Company Address	NW-07-301, NANOPOLIS SUZHOU, 99 JINJIHU AVENUE SUZHOU INDUSTRIAL PARK JANGSU PROVINCE CHINA

Labeler Identification Code: B785 [Verify LIC] (?)

Product / Catalogue Number: (?)

Unit of Measure / Package Indicator: 0 (?)

[Continue] [Clear]

HIBCC UDI Suite – Calculate Check Character

Access HIBCC UDI Suite

Create, Calculate, and Confirm UDI Information with HIBCC's suite of cloud-based tools

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HIBC Check Character Modulo 43 Generator

+B785ABC1230

Enter UDI / bar code data (one data string per line)

Generate Check Character

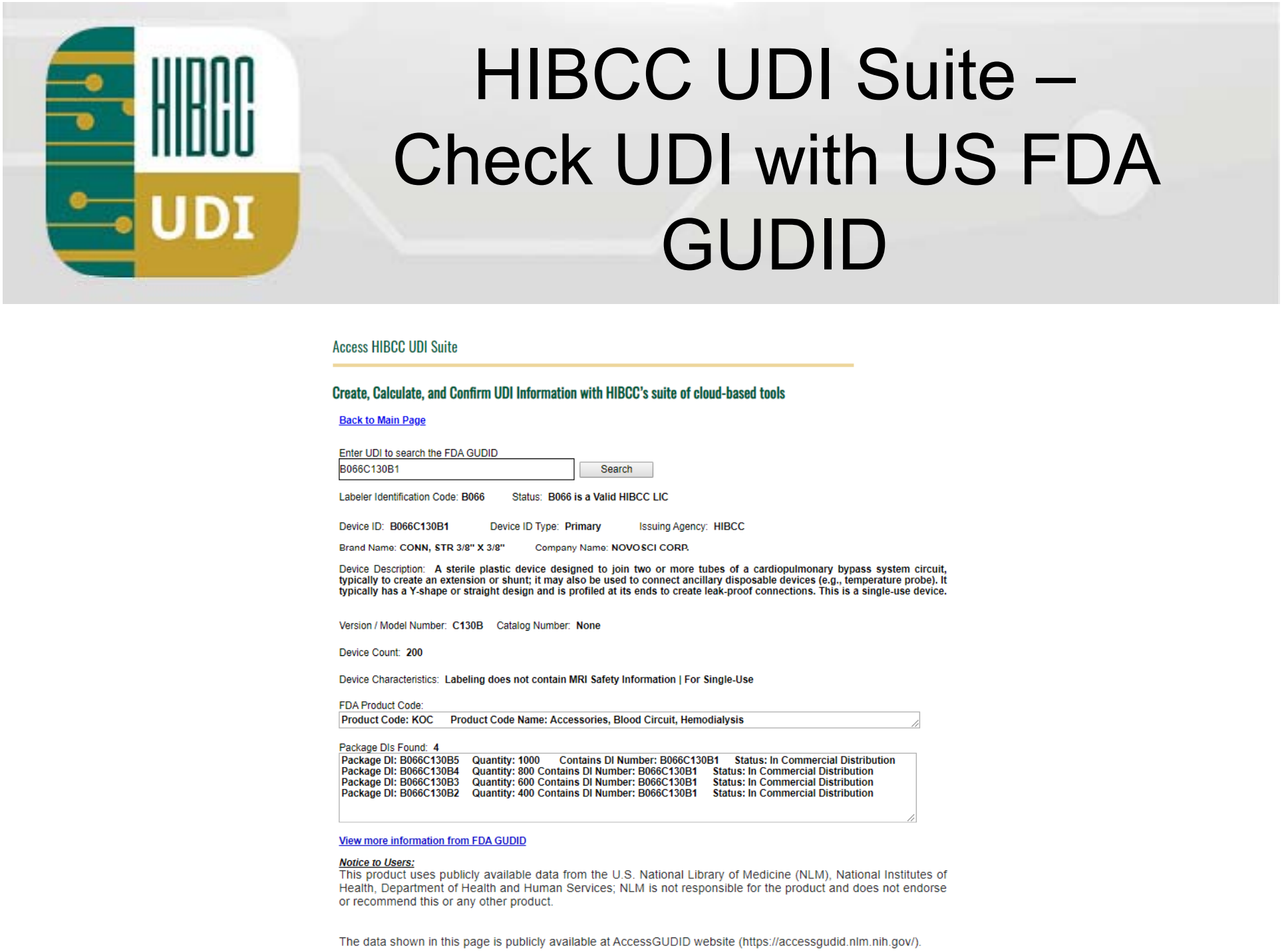
	UDI / Bar code data	Check Character	UDI with Check Character	Human Readable Interpret
1	+B785ABC1230	P	+B785ABC1230P	*+B785ABC1230P*

Each of the HIBC LIC Standard data structures employs a Modulo 43 Check Character for additional data security. The Check Character is the Modulo 43 sum of all the character values in a given message, and is printed as the last character in a given message, preceding the Stop Character. Leading and trailing asterisk "*" characters in the human-readable interpretation are not used in calculating the Check Character and are only represented in the human-readable interpretation.

When do I include a Check Character?

The HIBC Check Character must be included in the bar code and human-readable interpretation on the device label. The HIBC Check Character is not included in the Device Identifier submitted to the FDA's GUDID.

HIBCC UDI Suite – Check UDI with US FDA GUDID



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.