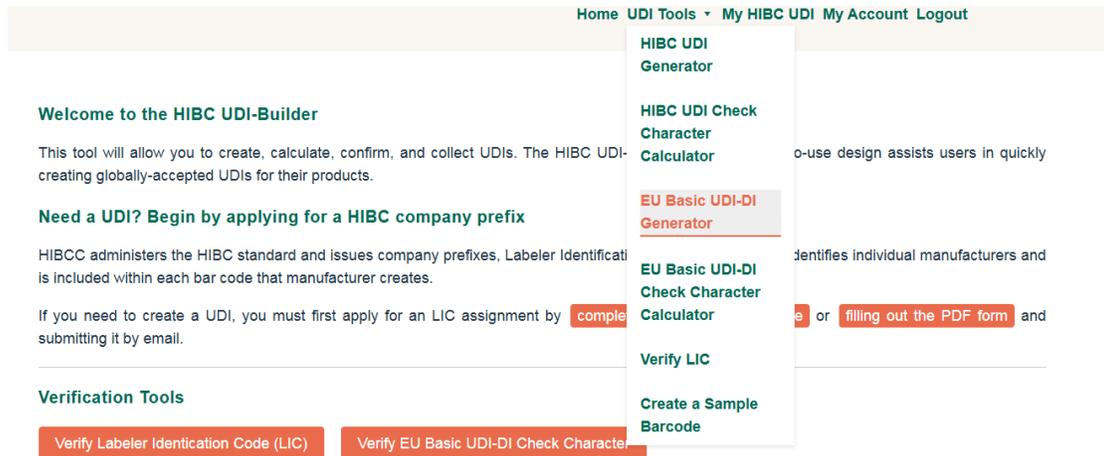




HIBCC UDI-Builder: Generate a Basic UDI=DI

Generate a Basic UDI-DI

1. Navigate to the EU Basic UDI-DI Generator page (can be found under UDI Tools).



2. Read the [HIBCC Basic UDI-DI Guidance](#) prior to using the tool.

Note: The Basic UDI-DI is an additional identifier required for the European Union (EU). It cannot be used in place of the UDI-DI.

HIBCC Basic UDI-DI Generator

The HIBCC Basic UDI-DI allows manufacturers to link and identify medical devices that share the same intended purpose, risk classification, and key design or manufacturing characteristics.

It fulfills the Basic UDI-DI requirements outlined in the European Union's Medical Device Regulation (MDR) and In-Vitro Diagnostic Regulation (IVDR). This identifier is mandatory for inclusion in the EU's EUDAMED database and must be referenced in key documents such as certificates and technical files.

The HIBCC Basic UDI-DI is assigned by the manufacturer following specific guidelines, but it does not appear on device packaging.

For additional guidance, refer to [HIBCC Basic UDI-DI Guidance](#).

3. The "Enter LIC" field will already be populated with the LIC associated with your account. To update the name or address associated with your LIC, please contact info@hibcc.org

Generate Basic UDI-DI

Global Model Identifiers must be 1 to 17 alphanumeric characters and are case-sensitive. If generating multiple Basic UDI-DIs, list each one on a separate line. You may enter up to 500 global model identifiers. Duplicates will be removed automatically.

Enter LIC:

A999

HIBCC DEMO ACCOUNT
2525 E ARIZONA BILTMORE CIR
PHOENIX, AZ, 85016, US

Generate multiple Basic UDI-DI

Global Model Identifier:

Generate

4. Enter a Global Model Identifier, assigned by the LIC-holder to represent devices with the same intended purpose, risk class, and essential design and manufacturing characteristics. Global Model Identifiers must be 1 to 17 alphanumeric characters and are case-sensitive.

Global Model Identifier:

GLOBALMODEL123

Generate

5. Click "Generate" to create the Basic UDI-DI. All data should be exported and stored internally.

Note: All HIBC Basic UDI-DIs begin with "++" and end with a two-character check sum.

Generate

Basic UDI-DI:

Global Model Identifiers Entered: 1 | Duplicates Removed: 0 | Basic UDI-DI Generated: 1, showing up to 50 records per page.

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Export: [CSV](#) [Excel](#)

LIC	Global Model Identifier	Basic UDI-DI	Check Characters
A999	GLOBALMODEL123	++A999GLOBALMODEL1237L	7L