Global Trade Identification Numbers (GTIN)

In 2013, the Food and Drug Administration (FDA) began requiring a unique device identification system designed to adequately identify devices through distribution and use. It is required that manufacturers include a unique device identifier (UDI) on device labels and packages. Each UDI is made up of two parts: 1) A device identifier (DI), which is a mandatory, fixed portion of a UDI, and 2) A production identifier, which is a conditional, variable portion of the UDI. The UDI identifies the manufacturer of the device, as well as the Global Trade Identification Number (GTIN), which uniquely identifies the specific version or model of a device. The GTIN is a 14-digit number found above the barcode on product packaging. Each product model number has a unique GTIN.

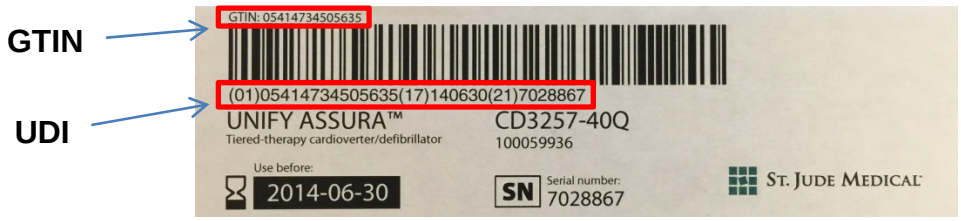

Figure 1: GTIN above the barcode on device packaging.

Additionally, the FDA provides the AccessGUDID database, where GTIN numbers for all manufacturers can be found. This database is available at: **https://accessgudid.nlm.nih.gov/**

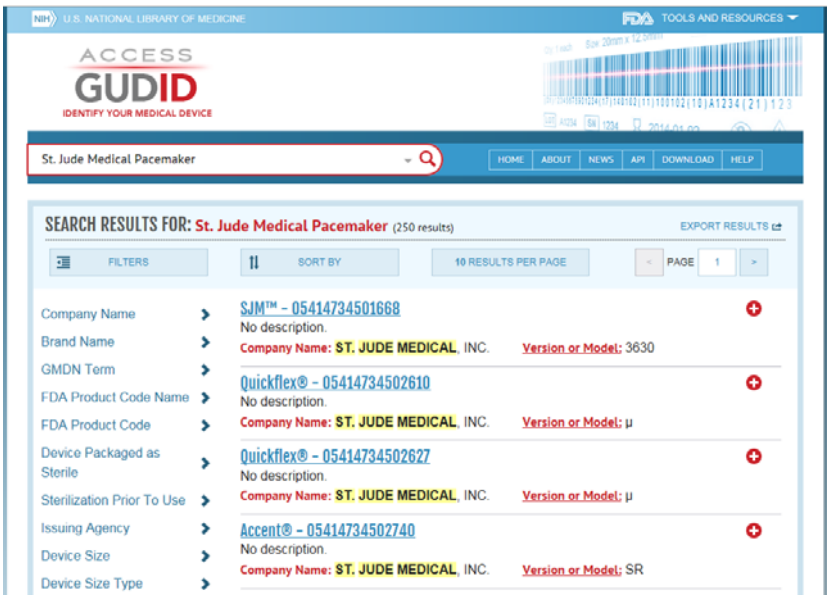

Figure 2: Example of AccessGUDID database GTIN lookup.

If you have any questions or would like to discuss this topic in greater detail, please contact St. Jude Medical CRM Technical Services.

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