5 STEPS TO FDA UDI LABELING COMPLIANCE

1 OBTAIN A DUNS NUMBER

All device labelers must obtain a Data Universal Numbering System (DUNS) number, as they are used to identify labeler organizations in GUDID.

Registrar Corp can obtain a DUNS number for your facility at no cost.

2 IDENTIFY YOUR GMDN CODES

Device labelers are required to identify a Global Medical Device Nomenclature (GMDN) code for each device submitted to the GUDID.

Registrar Corp can help you with this process.

3 GATHER YOUR UDIS

UDIs have a device identifier (DI) and a production identifier (PI). The DI must be issued by an FDA accredited agency. The PI is determined by production information, such as the lot or batch number. A separate UDI is needed for every version or model of each device.

4 APPOINT REGISTRAR CORP AS YOUR UDI REGULATORY CONTACT

Registrar Corp will setup your GUDID account, help determine the UDI requirements applicable to your specific devices, and facilitate your communications with FDA.

5 HAVE REGISTRAR CORP SUBMIT YOUR DEVICE DATA TO GUDID

Registrar Corp can guide you through the steps above as well as submit your device data to FDA's GUDID as required.

GET STARTED NOW: WWW.FDA-UDI.COM

Registrar Corp