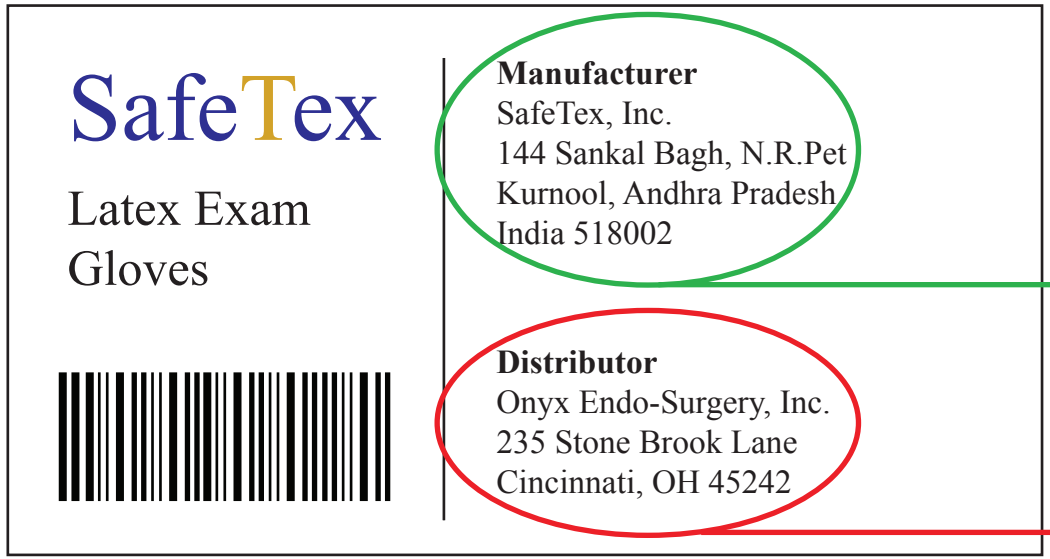
Unique Device Identifier (UDI) Labeler Responsibilities

FDA defines a labeler as:

(1) Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label; and

(2) Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.



Typically, the labeler is the **owner of the brand**.

A distributor adding its contact information to the label **does not** necessarily make it the labeler. If a distributor sells a product under its **own brand**, the distributor may be the labeler.

When the manufacturer does not own the brand, the manufacturer is not the labeler. In this scenario, RegMed buys catheters from CBI Medical Products and markets the devices under Reg Med's brand. As such, **RegMed would be considered the labeler**.

Registrar Corp