FLOTEC

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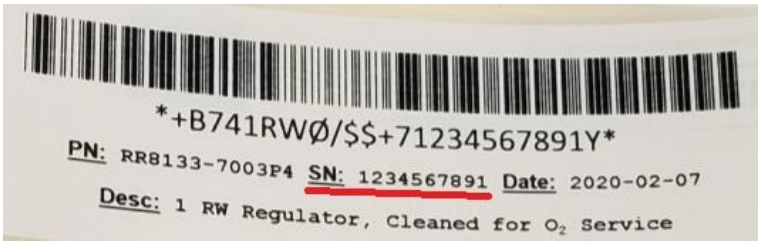
Unique Device Identification - UDI

The FDA established the **Unique Device Identification** system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use. When fully implemented, the label of most devices will include a **Unique Device Identifier** (UDI) in human and machine-readable form, which will ultimately improve patient safety, modernize device post market surveillance, and facilitate medical device innovation.

In general, the UDI final rule requires device labelers (typically, the manufacturer) to:

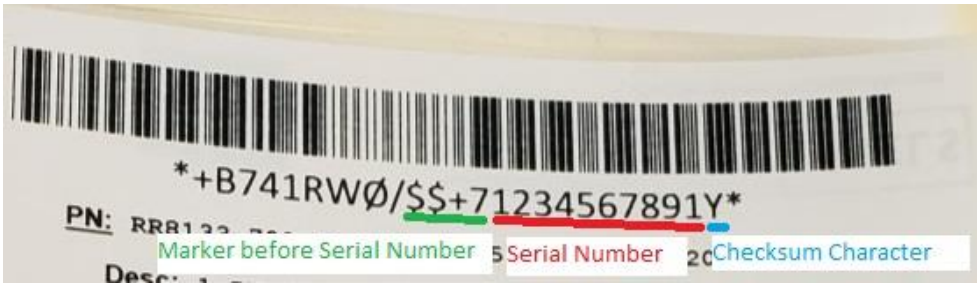
1. Include a **Unique Device Identifier** (UDI), issued under an FDA-accredited issuing agency's UDI system, on device labels, device packages, and in some instances, directly on the device.
2. Submit device information to the Global Unique Device Identification Database (GUDID).

Flotec has made the change to our individual box labels for Regulators, Flowmeters, and Mass Casualty Assemblies. Before the change, the barcode just contained the serial number. Now the barcode and human-readable text have additional information. The serial number is still presented by itself in human-readable text. See example below. If you have any questions about the new label, contact Flotec's regulatory department at QA@floteco2.com.



Special Note for Barcode-Reading Systems Developers:

Our label contains an UDI number that is compliant with the HIBCC format. It is presented as both barcode and plaintext. If you are using automated software to get the serial number from the barcode, the serial number can be obtained by scanning the barcode, and then extracting the substring between the lot/serial number marker ("$$7" or "$$+7") and the checksum character (the last character). The checksum character can also be used to verify that the scan was successful. For more information about the UDI format Flotec uses, go to hibcc.org, or contact Flotec at QA@floteco2.com.



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