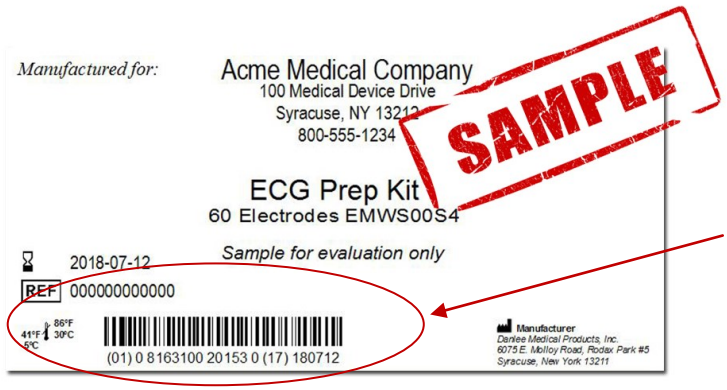
Unique Device Identifier (UDI)

Danlee Medical Products, Inc.

Deadline: September 24, 2018

↓ Does your hook-up kit label look like this?



What is UDI?

The US Food and Drug Administration (FDA) has established a unique device identification system to adequately identify medical devices through their distribution and use. As a result of this implementation, most medical devices must bear a unique device identifier (UDI) on their label that is printed both in alphanumeric and machine readable forms (barcode). Patient Holter and event recording kits (hook-up kits) are classified as convenience kits by FDA standards and are subject to UDI medical device regulation.

Worried About The Deadline?

All convenience kit users/manufacturers (labelers) are mandated by September 24, 2018 to comply with these new rules; meaning all kit labels after this date ***must*** bear a UDI. Those that do not comply with these new rules are subject to consequences defined by the FDA.

How We Can Help!

Are your products UDI compliant? Danlee can take the headache and stress of UDI compliance off your 2018 to do list. We currently produce over 450 different variations of hook-up kits. We've been FDA/UDI compliant since August of 2016. This is our business. This is what we do.

Benefits of Using Danlee:

- FDA registered and UDI compliant - ***check!***
- Private labeling capabilities - ***check!***
- Fast & efficient delivery - ***check!***
- High quality products - ***check!***

Give us the opportunity to help.

Women's Business Enterprise National Council WBENC

Call 1.800.433.7797 today!

Danlee Medical Products, Inc. • 6075 E. Molloy Road—Rodax Business Park—Building #5 • Syracuse, New York 13211
Phone: 1.800.433.7797 or 315.431.0143 • Fax: 315.431.0149 • www.danleemedical.com • info @danleemedical.com