Leaders in Noninvasive Medical Monitoring

8 August 2016

Dear Valued Nonin Medical Customer:

This letter is an update to the notice sent February 2015 regarding Nonin Medical's initiative regarding labeling changes to include Unique Device Identifier (UDI) and barcodes on package labels in accordance with FDA regulation GS1 Healthcare standards required for Class 2 medical device compliance on 24 September 2016.

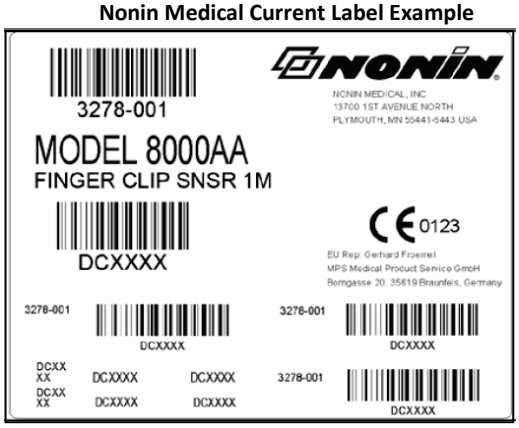
NONIN BRANDED PRODUCTS

Progress is made on assigning UDIs to Nonin-branded FDA class 2 products, with the intent of having all uploads into the FDA database by end of August 2016.

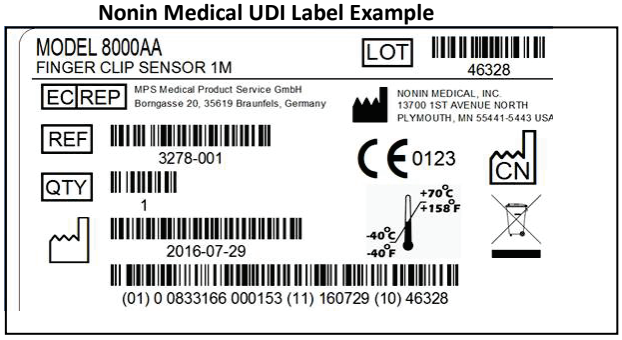
NONIN OEM PRODUCTS

Nonin will be placing a UPC on the package label for OEM components, such as Xpod LP, iPod, signal processors, etc. This will not be a UDI and Nonin will not be entering these GTIN numbers into FDA's database; this is the responsibility of the host device manufacturer. For the 3150, 9560 and 3230, Nonin will be adding a UDI to the package label and entering these GTIN numbers in the FDA's database. Below is an example of a current label, and then a label with UDI, for comparison.

Nonin Medical Current Label Example



Nonin Medical UDI Label Example



Please note, during the transition to the UDI label format, you may see a mixed inventory of product labeling; you may also see cosmetic changes, including global recognition symbols.

FDA allows three years after 24 September 2016 for all inventories in the field to transition to package labels with the UDI; this does not make anyone exempt from entering the UDIs into FDA's database for Class 2 products by 24 September 2016.

For more information about Nonin's implementation and transition to meet the UDI package requirements, please see our FAQ at http://www.nonin.com/documents/UDI_FAQ.pdf. All Nonin-specific questions should be directed to Regulatory@nonin.com.

Sincerely,

The Nonin Medical GUDID Labeling Team

Nonin Medical, Inc.'s Transition to FDA's Upcoming Unique Device Identification for Medical Devices

Dear Nonin Medical Customer:

Beginning in January 2015, Nonin Medical initiated labeling changes to include Unique Device Identifier (UDI) information and barcodes on product labels per new U.S. Food and Drug Administration (FDA) GS1 Healthcare standards.

During the transition to the UDI label format, you may see a mixed inventory of product labeling, but both formats will include all existing Nonin Medical label data. All container labeling will be transitioned to include UDI information and barcodes by the FDA's Class II Medical Device mandated date of September 24, 2016. All product labeling will be transitioned to add UDI information and barcodes by September 24, 2018.

For more information about these new standards, please visit www.gs1.org/healthcare or visit www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/.

All Nonin-specific questions should be directed to Nonin Medical at info@nonin.com.

Sincerely,

Nonin Medical, Inc.

Unique Device Identifier FAQ

Beginning in January 2015, Nonin Medical initiated labeling changes to include Unique Device Identifier (UDI) information and barcodes on product labels per new U.S. Food and Drug Administration (FDA) GS1 Healthcare standards.

During the transition to the UDI label format, you may see a mixed inventory of product labeling, but both formats will include all existing Nonin Medical label data. All container labeling will be transitioned to include UDI information and barcodes by the FDA's Class II Medical Device mandated date of September 24, 2016. All product labeling will be transitioned to add UDI information and barcodes by September 24, 2018.

All Nonin-specific questions should be directed to Nonin Medical at info@nonin.com.

1. What is UDI?

- A UDI is a unique numeric or alphanumeric identification code assigned to medical devices by the labeler (e.g., manufacturer) of the device. A UDI typically includes two segments: a "device identifier" (DI) that identifies the labeler and specific version of the device; and a "production identifier" (PI), such as a lot or serial number.
- The Global Unique Device Identification Database (GUDID), is a publicly searchable database administered by the FDA that serves as a reference catalog for every device with a UDI.
- The FDA website (www.FDA.gov) has information that explains the UDI rule, the GUDID data elements and other relevant information. The following link is to the FDA's UDI website:
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm
- The FDA published a set of FAQs that may also be helpful:
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM410439.pdf

2. Which Nonin devices are affected by this regulation?

Nonin distributes Class II devices and is working to ensure they comply with the UDI regulation.

3. Who does the U.S. FDA UDI Rule apply to?

The requirements of the U.S. FDA UDI Rule apply to "labelers" of medical devices. The labeler of each device is responsible for meeting labeling and Global UDI Database (GUDID) data submission requirements (as well as the direct part marking and date format requirements where applicable).

4. When a customer places an order, will anything change? Will the invoice and packing slip change?

No. Customers can continue to use the Nonin product catalog numbers to place orders. The invoice and packing slip will remain the same.

5. What is the standardized date format & when does the new date standard go into effect?

The U.S. FDA UDI Rule adopted the standard YYYY-MM-DD as the standardized format for dates on device labels. Dates on labels will have to be in the new format no later than the date on which the label of the device must bear a UDI. Consult the compliance schedule for the timelines.

6. What is the GUDID and how can data be accessed?

The GUDID serves as the repository of key device identification information, the UDI DI serves as the primary key to obtain device information in the database. The GUDID data attributes is a critical element of the FDA UDI regulation. Nonin will prepare a data set specific to each DI and upload the data to the GUDID in the required timeframe. The public will be able to search information from the GUDID about the device.

7. What about existing inventories? Do manufacturers have to remark them?

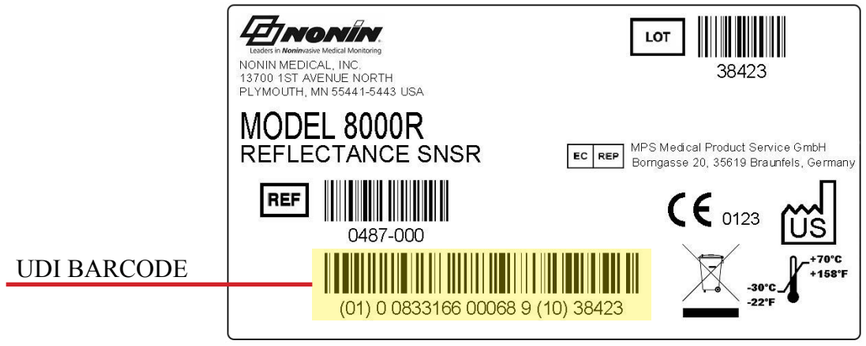
No, there are two exceptions for existing inventories:
- A device that is in commercial distribution prior to the applicable compliance date does not have to comply with the final rule.
- Devices that are manufactured and labeled before their compliance date have an exception from the rule. However, this exception expires 3 years after the compliance date for that device.

8. Do all devices need to be directly marked with their UDI?

No. The rule only requires direct part marking for re-usable medical devices that need to be reprocessed before reuse.

9. Will UDI drive any changes with the barcodes on product labels?

The FDA stated in the final FDA rule: "FDA does not require the use of specific forms of AIDC or specific AIDC technologies." Nonin Medical will select the GS1 bar code symbol (Nonin's selected UDI System) appropriate to the size of the package and the scanning environment (for instance, bedside scanning versus scanning in a warehouse). 2D Datamatrix symbols may be used on small packages. Larger packages may use GS1-128 linear bar codes.



10. What are key FDA regulatory milestones for UDI?

The FDA has established a specific timetable by which medical devices must be compliant. Class III devices are the first group of devices that must comply, followed by Class II and Class I. If these dates are not met, the product cannot be distributed in the U.S. The FDA has also granted an existing inventory exception of 3 years for a finished device manufactured and labeled prior to the UDI compliance date.

	Final Rule	Sept 24, 2014	Sept 24, 2015	Sept 24, 2016	Sept 24, 2018	Sept 24, 2020
Labels and Packages must contain UDI Dates must be formatted at YYYY-MM-DD Products must be submitted to FDA UDI Database	Final Rule Published September 24, 2013	Class III	Implantable or life sustaining/ supporting	Class II	Class I	
Products intended to be used more than once *must have direct part marking*			Implantable or life sustaining/ supporting	Class III	Class II	Class I