UDI Compliance Policies and UDI Rule Compliance Dates

Is Your Product a Medical Device?
Determine if your product meets the definition of a device (/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device).

How to determine device class
Classify your medical device (/medical-devices/overview-device-regulation/classify-your-medical-device)

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UDI Compliance Policies

The FDA established compliance dates in conjunction with the Unique Device Identification System final rule (UDI rule) (https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system). Since publication of the UDI rule in 2013, and based on stakeholder feedback, the FDA has issued compliance policies for specific UDI requirements. The tables below represent the current UDI compliance policies.

Note: Compliance policies for all non-sterile Class III, Class II, and implantable, life-supporting or life-sustaining (I/LS/LS) devices are no longer in effect; these devices should bear a unique device identifier (UDI) unless an FDA-granted alternative or exception applies. For sterile Class III, Class II, and I/LS/LS devices, consult the FDA webpage on FDA-granted alternatives. More information on alternatives and exceptions, including FDA-granted alternatives and exceptions, can be found on UDI Exceptions and Alternatives (/medical-devices/unique-device-identification-system-udi-system/udi-exceptions-and-alternatives).

UDI Policy Regarding Class I and Unclassified Devices, Direct Marking, and GUDID Requirements for Certain Devices

On July 22, 2022, the FDA posted the final guidance: **Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marking, and Global Unique Device Identification Database Requirements for Certain Devices (/regulatory-**

information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices). This final guidance describes the FDA's compliance policy regarding Global Unique Device Identification Database (GUDID) submission requirements for certain Class I devices considered consumer health products. The update to this guidance reflects the finalization of the draft guidance "Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices", which was issued October 14, 2021, and following the consideration of public comments. This final guidance describes the FDA's compliance policy regarding GUDID submission requirements for certain Class I devices considered consumer health products. Additionally, the FDA does not intend to enforce the GUDID submission requirements for Class I and unclassified devices, other than implantable, life-supporting or life-sustaining devices, regardless of whether they are consumer health products, before December 8, 2022. I/LS/LS devices, including Class I I/LS/LS devices, are already expected to comply with GUDID submission requirements. This new date provides a 75-day extension of an existing FDA compliance policy published in the July 2020 version of this guidance.

This guidance (/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices) also describes the FDA's direct mark compliance policy. The FDA does not intend to enforce the direct mark requirements under 21 CFR 801.45 for finished Class III, LS/LS, and Class II non-sterile devices, requiring a direct mark, that are manufactured and labeled prior to their

applicable direct mark compliance date, and that remain in inventory, as well as for finished Class I and unclassified devices that are non-sterile, that are manufactured and labeled prior to September 24, 2022, and that remain in inventory, provided the device bears a non-UDI direct mark and the labeler has developed a method by which, using the non-UDI mark, the UDI may be made available. For certain sterile devices, the FDA has issued a UDI alternative under 21 CFR 801.55, which can be found UDI Exceptions and Alternatives (/medical-devices/unique-device-identification-system-udi-system/udi-exceptions-and-alternatives).

The compliance policy described in the guidance does not apply to I/LS/LS devices, including Class I or unclassified I/LS/LS devices; labelers of these devices must already be in compliance with UDI requirements. Under 21 CFR 801.30(a)(2), Class I CGMP-exempt devices are excepted from UDI requirements.

The table below summarizes the compliance policies set forth in this guidance by device type

Device Type	**UDI Rule Requirement**	**Compliance Policy**
Class I and unclassified devices, other than I/LS/LS devices, that are required to bear a UDI	UDI labeling (21 CFR 801.20 & 801.50)	The FDA does not intend to enforce prior to **September 24, 2022** (see section III.A)
Class I and unclassified devices, other than I/LS/LS devices	Standard date format (21 CFR 801.18)	The FDA does not intend to enforce prior to **September 24, 2022** (see section III.A)
Class I and unclassified devices, other than I/LS/LS devices, that are required to bear a UDI	GUDID submission (21 CFR 830.300)	The FDA does not intend to enforce prior to **December 8, 2022*** (see section III.B.2 for Class I devices and III.C for

		unclassified devices)
Consumer health products	GUDID submission (21 CFR 830.300)	See section III.B.1**
Class I and unclassified devices, other than LS/LS devices, that are required to bear a UDI and be directly marked with a UDI	Direct mark (21 CFR 801.45)***	The FDA does not intend to enforce prior to **September 24, 2022** (see section IV.B)
Non-sterile Class I devices and unclassified devices, including Class I and unclassified device constituents of a co-packaged combination product or kit other than LS/LS devices that are manufactured and labeled prior to September 24, 2022	Direct mark (21 CFR 801.45)	The FDA does not intend to enforce UDI direct mark requirements when the device's UDI can be derived from other information directly marked on the device (see section IV.B)
Non-sterile Class II devices, other than LS/LS devices that are manufactured and labeled prior to September 24, 2018	Direct mark (21 CFR 801.45)	The FDA does not intend to enforce UDI direct mark requirements when the device's UDI can be derived from other information directly marked on the device (see section IV.A)
Non-sterile LS/LS devices that are manufactured and labeled prior to September 24, 2015	Direct mark (21 CFR 801.45)	The FDA does not intend to enforce UDI direct mark requirements when the device's UDI can be derived from other information directly marked on the device (see section IV.A)

Non-sterile Class III devices that are manufactured and labeled prior to September 24, 2016	Direct mark (21 CFR 801.45)	The FDA does not intend to enforce UDI direct mark requirements when the device's UDI can be derived from other information directly marked on the device (see section IV.A)

* Denotes changes from the previous version of the guidance (issued in July 2020).

** For purposes of the guidance (/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices), "consumer health products" means 510(k)-exempt Class I devices that are sold directly to consumers over-the-counter in brick-and-mortar and/or online stores and that do not fall within one or more of the categories identified in section III.B.2.

*** Implantable devices are not required to be directly marked with a UDI. See Guidance for Industry and FDA Staff: Unique Device Identifier System: Frequently Asked Questions, Vol. 1 (/media/89275/download).

Consigned or Loaned Devices

The FDA recognizes that some devices are consigned or loaned to hospitals or other healthcare facilities prior to the applicable UDI labeling compliance date or are with a sales representative in the field pending sale prior to that UDI compliance date. In the FDA's guidance, Unique Device Identification: Direct Marking of Devices: Guidance for Industry and Food and Drug Administration Staff (/regulatory-information/search-

fda-guidance-documents/unique-device-identification-direct-marking-devices), the FDA provided the compliance policy set forth in the chart below.

Device Type	UDI Rule Requirement	Compliance Policy
All classes of devices (sterile and non-sterile) that were consigned or loaned prior to applicable label compliance date identified below: • Class III - 09/24/2014 • LS/LS - 09/24/2015 • Class II - 09/24/2016 • Class I - 09/24/2018	Labeling (21 CFR 801.20) Direct mark (21 CFR 801.45) Date format (21 CFR 801.18)	To the extent those devices are required to comply with the UDI rule requirements, the FDA does not intend to enforce compliance with such requirements for those devices (see section III). Such devices are still required to submit information to GUDID consistent with 21 CFR 830.300.

Legacy FDA Identification Numbers

The UDI Rule includes a provision that rescinds any National Health Related Item Code (NHRIC) or National Drug Code (NDC) number assigned to a medical device (21 CFR 801.57). On the date a medical device must bear a UDI on its label, (/medical-devices/unique-device-identification-system-udi-system/udi-compliance-policies-and-udi-rule-compliance-dates) any NHRIC or NDC numbers assigned to the device are rescinded and may no longer be on the device label or package (21 CFR 801.57(a)). If a device is not required to bear a UDI on its label, any NHRIC or NDC number assigned to that device is rescinded as of September 24, 2018, and may no longer be on the device label or on any device package (21 CFR

801.57(b)). The Enforcement Policy Regarding Use of National Health Related Item Code and National Drug Code Numbers on Device Labels and Packages - Guidance for Industry and Food and Drug Administration Staff (/regulatory-information/search-fda-guidance-documents/enforcement-policy-regarding-use-national-health-related-item-code-and-national-drug-code-numbers), issued on May 21, 2021, describes the Agency's enforcement policy regarding the regulatory prohibition against providing NHRIC or NDC numbers on device labels and device packages.

This guidance indicates that the FDA does not intend to object to the use of legacy FDA identification numbers on device labels and device packages, for finished devices that are manufactured and labeled prior to September 24, 2023. This policy applies to the requirement that labelers no longer provide an NHRIC or NDC number on a device label or device package as of the dates specified under 21 CFR 801.57(a)-(b); it does not extend to any of the other requirements under the UDI Rule. **New labeler codes are not assigned by the FDA for the purposes of assigning NDCs to non-drug products or for use under a system for the issuance of UDIs.**

Device Type	UDI Rule Requirement	Compliance Policy
All devices	Discontinuation of legacy identification numbers (21 CFR 801.57)	The FDA does not intend to object to the use of legacy NHRIC and NDC numbers on device labels and device packages, with respect to finished devices that are manufactured and labeled prior to September 24, 2023.

UDI Rule Compliance Dates and Requirements by Device Type

The tables below represent the UDI requirements and compliance dates established by the FDA in the 2013 UDI Rule (https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system). Since publication of the UDI Rule and based on stakeholder feedback, the FDA has issued compliance policies for specific requirements.

Devices Excepted From or Not Subject to UDI Labeling Requirements

Compliance Date	Requirements
September 24, 2018	Dates on the labels of devices, excepted from or not subject to the UDI labeling requirements, must be formatted as required by § 801.18.

Class I and Unclassified Medical Devices

Compliance Date	Requirements
September 24, 2020	Class I devices, and devices that have not been classified into Class I, Class II, or Class III that are required to be labeled with a UDI, must a bear UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.
September 24, 2018	The labels and packages of Class I medical devices and devices that have not been classified into Class I, Class II, or Class III must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18.

	Data for Class I devices and devices that have not been classified into Class I, Class II, or Class III that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300. Class I stand-alone software must provide its UDI as required by § 801.50(b).

Class II Medical Devices

Compliance Dates	Requirements
September 24, 2018	A Class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.
September 24, 2016	The labels and packages of Class II medical devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Class II stand-alone software must provide its UDI as required by § 801.50(b). Data for Class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.

Class III Medical Devices and Devices Licensed under the Public Health Service Act (PHS)

Compliance Dates	Requirements
September 24, 2016	A Class III device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be

	used more than once and intended to be reprocessed before each use. § 801.45.
September 24, 2014	The labels and packages of Class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Data for these devices must be submitted to the GUDID database. § 830.300. A 1-year extension of this compliance date may be requested under § 801.55; such a request must be submitted no later than June 23, 2014. Class III stand-alone software must provide its UDI as required by § 801.50(b).

Implantable, Life-Supporting, and Life-Sustaining Medical Devices

Compliance Date	Requirements
September 24, 2015	The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. A device that is a life-supporting or life-sustaining device that is required to be labeled with a UDI must a bear UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. § 801.45. Stand-alone software that is a life-supporting or life-sustaining device must provide its UDI as required by § 801.50(b). Data for implantable, life-supporting, and life-sustaining devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.