U.S. FDA UDI Regulation and Recent Updates

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U.S. Food and Drug Administration

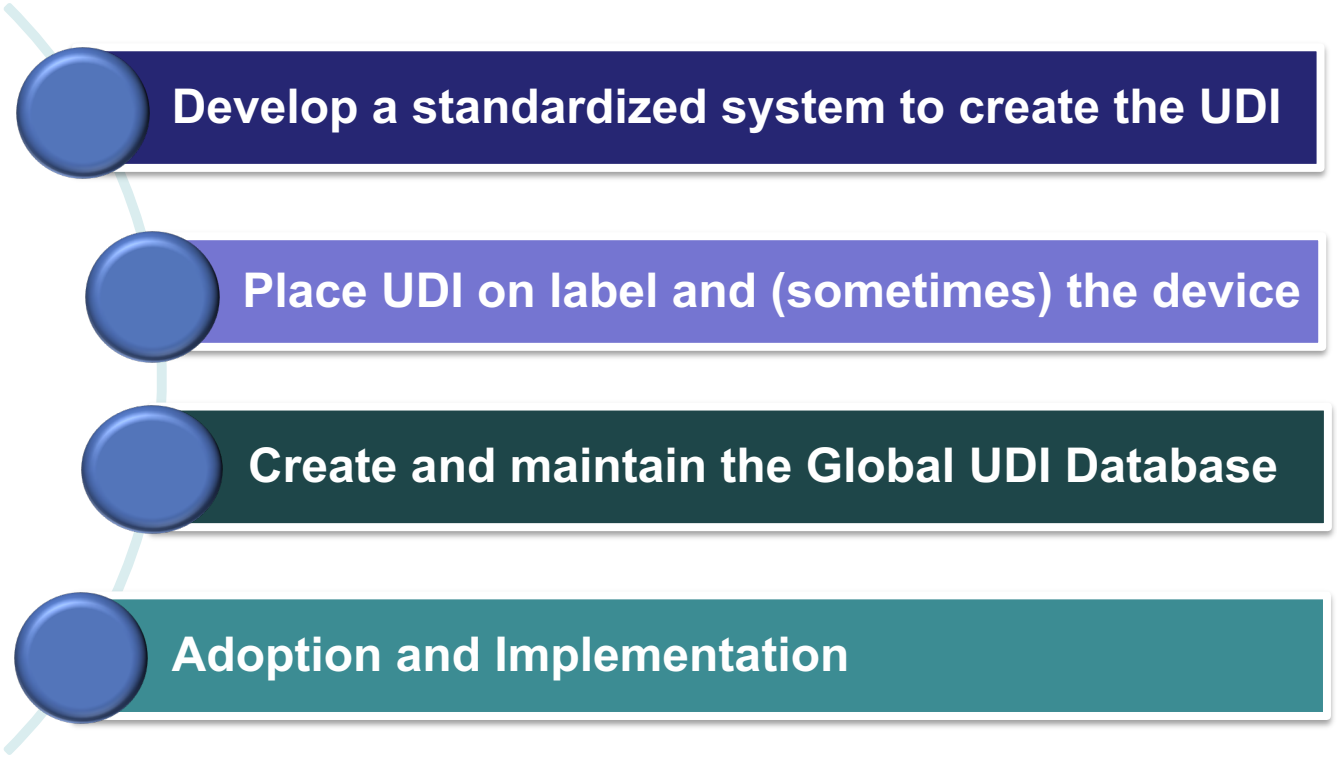
January 20, 2022

Establishing a UDI System

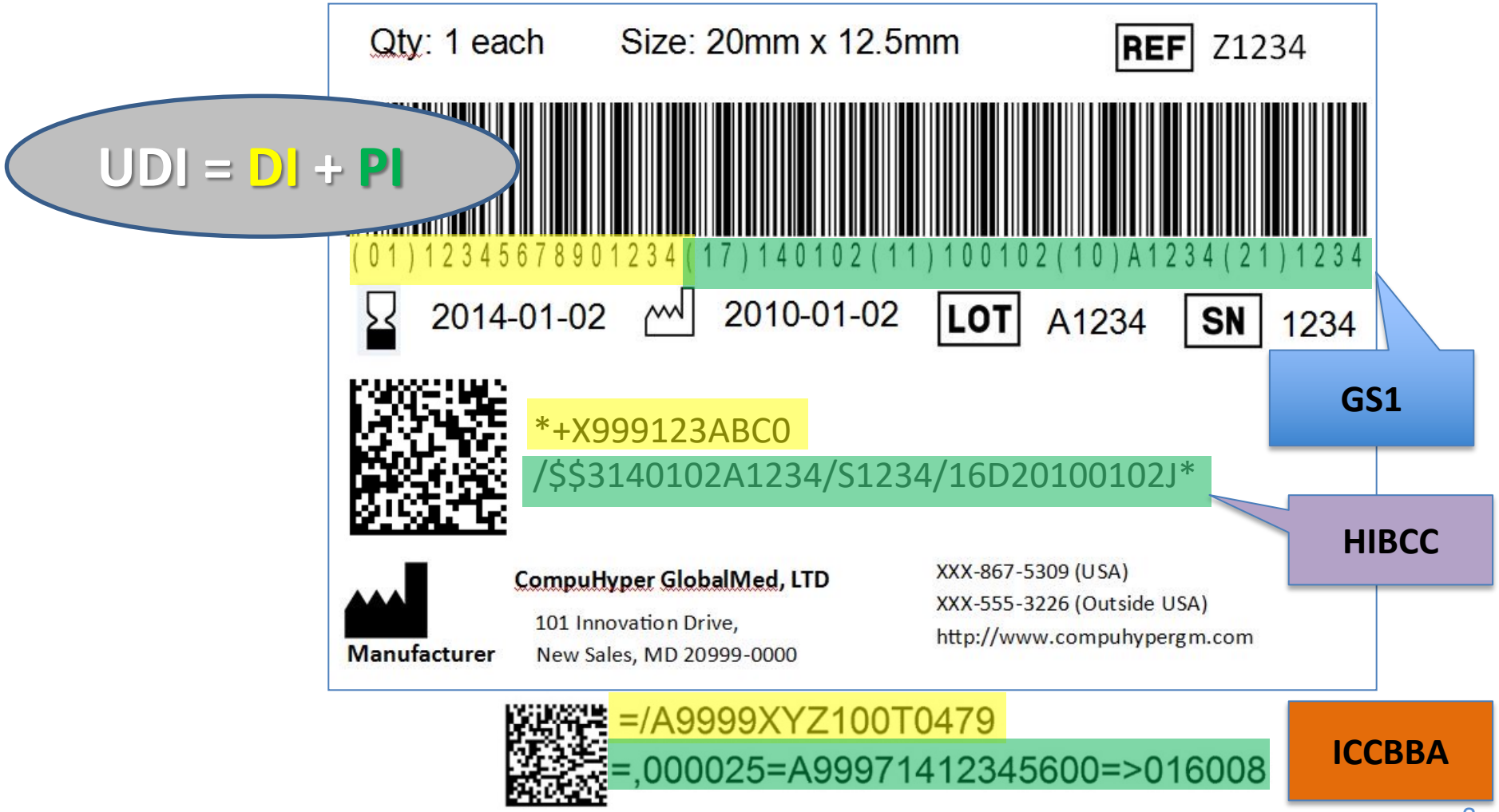
UDI Final Rule

[78 FR 58786]

Sept 24, 2013



Unique Device Identifier (UDI)



Implementation Timeframe

	Date	Must bear a UDI and Submit data to GUDID	Direct Marking (for certain intended uses)
✓	**Sep 24, 2014**	**Class III devices** Devices licensed under the PHS Act	
✓	**Sep 24, 2015**	Implantable, life-supporting and life-sustaining (I/LS/LS) devices	LS/LS devices
✓	**Sep 24, 2016**	**Class II devices** (not I/LS/LS)	Class III devices and devices licensed under the PHS Act
✓	**Sep 24, 2018**	Class I devices Unclassified devices (not I/LS/LS)	Class II devices (not LS/LS)
✓	**Sep 24, 2020**	**Class I devices** Unclassified devices (not I/LS/LS)	Class I devices Unclassified devices (not LS/LS)
	Sep 24, 2022	**Class I devices Unclassified devices (not I/LS/LS)**	**Class I devices Unclassified devices (not LS/LS)**

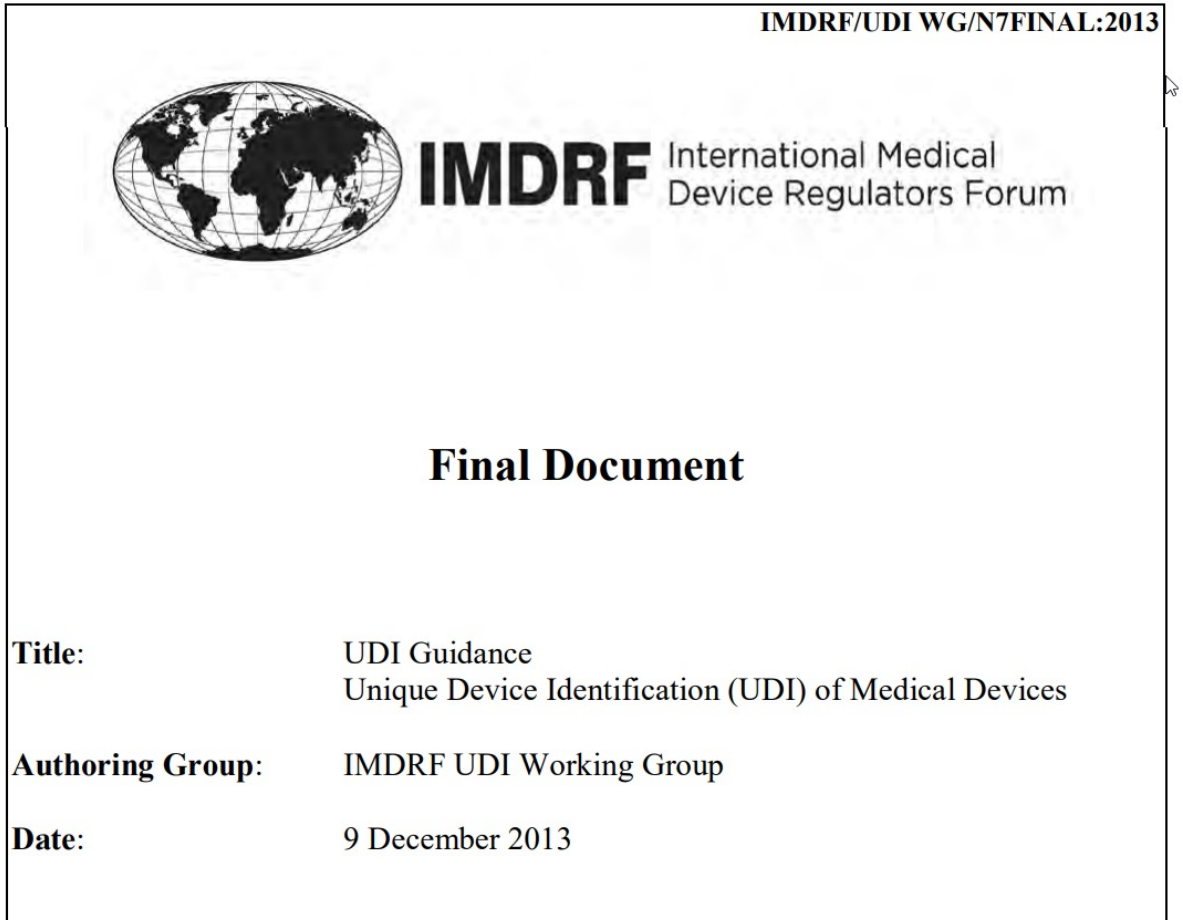
2018 Guidance

2020 Guidance

2018 Guidance

International Harmonization

IMDRF/UDI WG/N7 Final: 2013 UDI Guidance



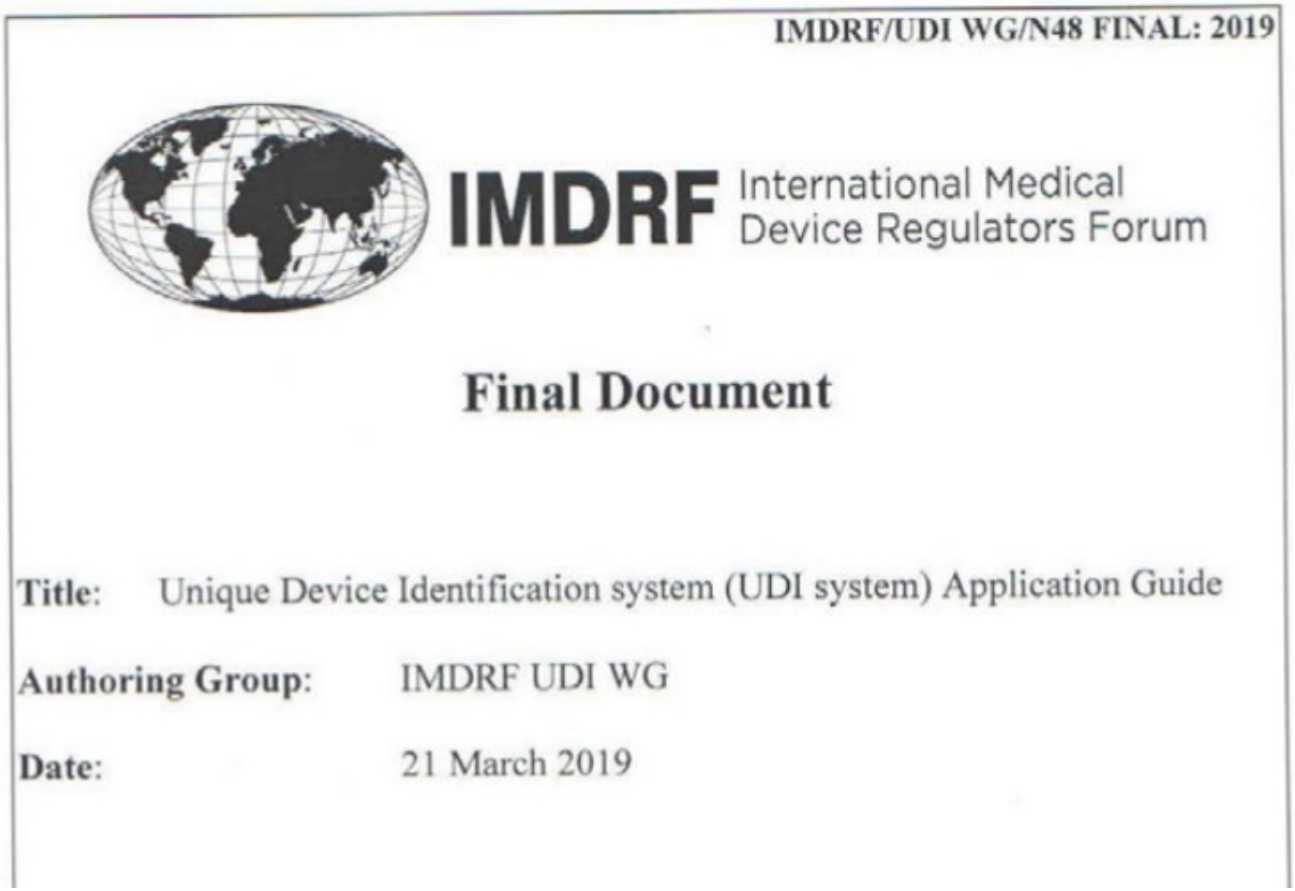
IMDRF/UDI WG/N7FINAL:2013

IMDRF International Medical Device Regulators Forum

Final Document

Title:	UDI Guidance Unique Device Identification (UDI) of Medical Devices
Authoring Group:	IMDRF UDI Working Group
Date:	9 December 2013

IMDRF/UDI WG/N48 Final: 2019 UDI System Application Guide



IMDRF/UDI WG/N48 FINAL: 2019

IMDRF International Medical Device Regulators Forum

Final Document

Title: Unique Device Identification system (UDI system) Application Guide

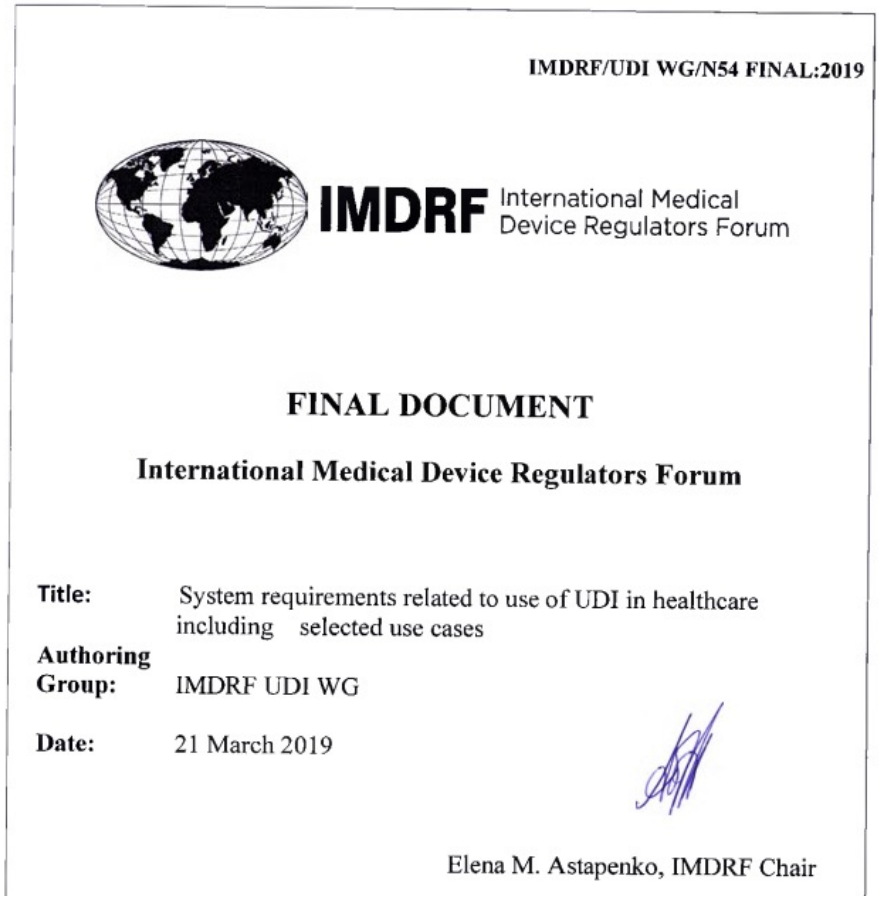
Authoring Group: IMDRF UDI WG

Date: 21 March 2019

IMDRF/UDI WG/N53 FINAL:2019

	A	B	C	D	E	F	G	H
1	Jurisdiction	IMDRF			European Union		United States	
2	Source	IMDRF/UDI WG/N7FINAL:2013 Section 9.2			http://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en		https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416106.htm	
3	Date revised				18-Feb-2019		18-Feb-2019	
4		Data Element #	Data Element	UDID Requirement	Data Element	EUDAMED Requirement	Data Element	GUDID Requirement
5	Device Identification & Description	--	--	--	Basic UDI-DI	R	--	--
6		1	UDI-DI (UDI type, e.g. GS1 GTIN, HIBC-LIC, ISBT-128 PPIC)	R	UDI-DI	R	Primary DI Number	R
7					Issuing Entity (UDI-DI)	R	Issuing Agency	R
8					Isuing Entity (Basic UDI-DI)	R	--	--
9		--	--	--	Single Registration Number	R	--	--
10		9	Brand Name	C	Name or Trade name (name of product)	R	Brand Name	R
11		11	Device model or version	R	Name or, if applicable, device model that identifies the BASIC UDI-DI Group in the technical documentation and/or certificate and declaration of conformity	R	Version or Model	R
12		12	Reference and/or catalogue number	C	Reference, article or catalogue number	R	Catalog Number	O
13		15	Additional product Description (optional) – Additional clinically relevant information, e.g. radio-opaque	O	Additional product Description	O	Device Description	O
14		--	--	--	Direct Marking (DM) DI	R	DM DI Different from Primary DI	C
15		--	--	--	--	--	DM DI Number	C
16		--	--	--	Issuing Entity (Secondary DI)	C	Issuing Agency (Secondary DI)	O
17		1	Additional device identifier(s) (if applicable) e.g. GS1, HIBC, or ISBT-128	C	Secondary UDI-DI	C	Secondary DI Number	O
18		--	--	--	--	--	Issuing Agency (Previous DI)	O
19		--	--	--	--	--	Previous DI Number	O
20		2	Unit of Use UDI-DI	R	Unit of Use (UoU) UDI-DI	C	Unit of Use DI Number	C
21		--	--	--	Quantity of devices	R	Device Count	R
22		--	--	--	Additional Trade Names	C	--	--

IMDRF/UDI WG/N54 Final: 2019 System requirements related to use of UDI in healthcare including selected use cases



IMDRF/UDI WG/N54 FINAL:2019

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: System requirements related to use of UDI in healthcare including selected use cases

Authoring Group: IMDRF UDI WG

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

U.S. FDA UDI Webpage

UDI Rule and Guidances, Training, Resources, and Dockets

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This page provides a comprehensive list of links to:

- UDI rule and guidances
- UDI training for industry
- UDI and GUDID technical documents
- UDI dockets

www.fda.gov/udi

UDI Form & Content Final Guidance

Figure 1 shows an example of a UDI in both easily readable plain-text and AIDC forms.

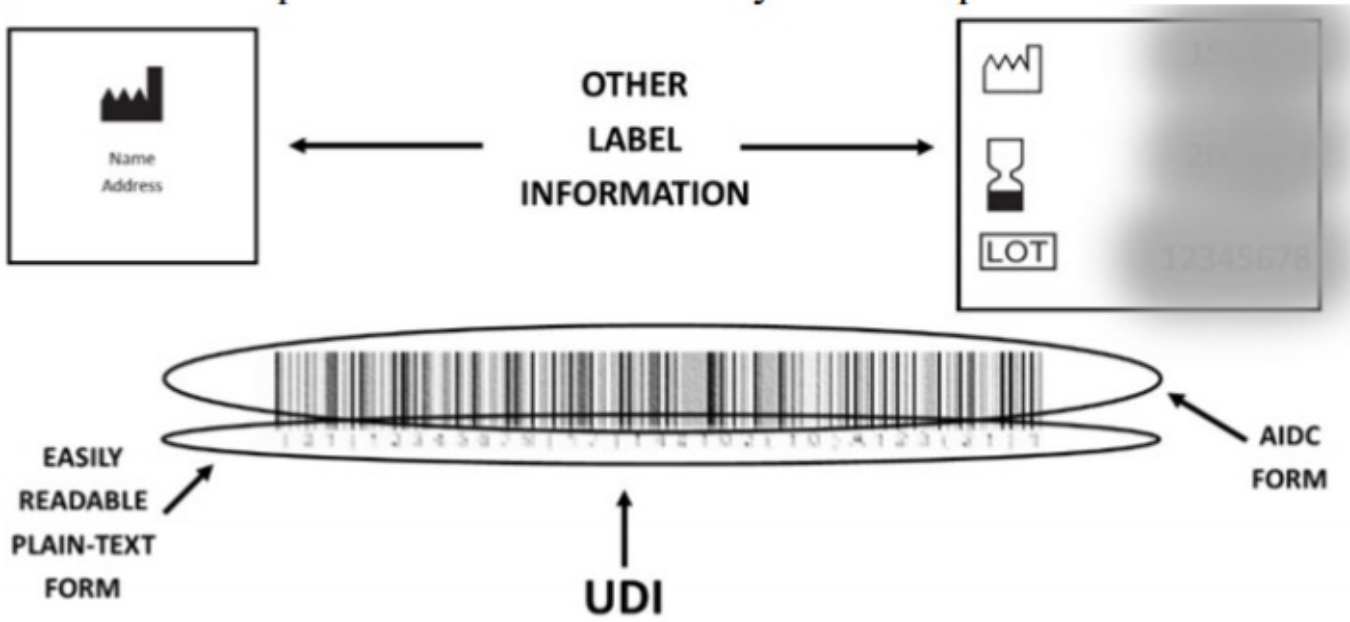


Figure 1. UDI in Easily Readable Plain-Text and AIDC Forms

Contains Nonbinding Recommendations

Draft – Not for Implementation

Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on October 14, 2021

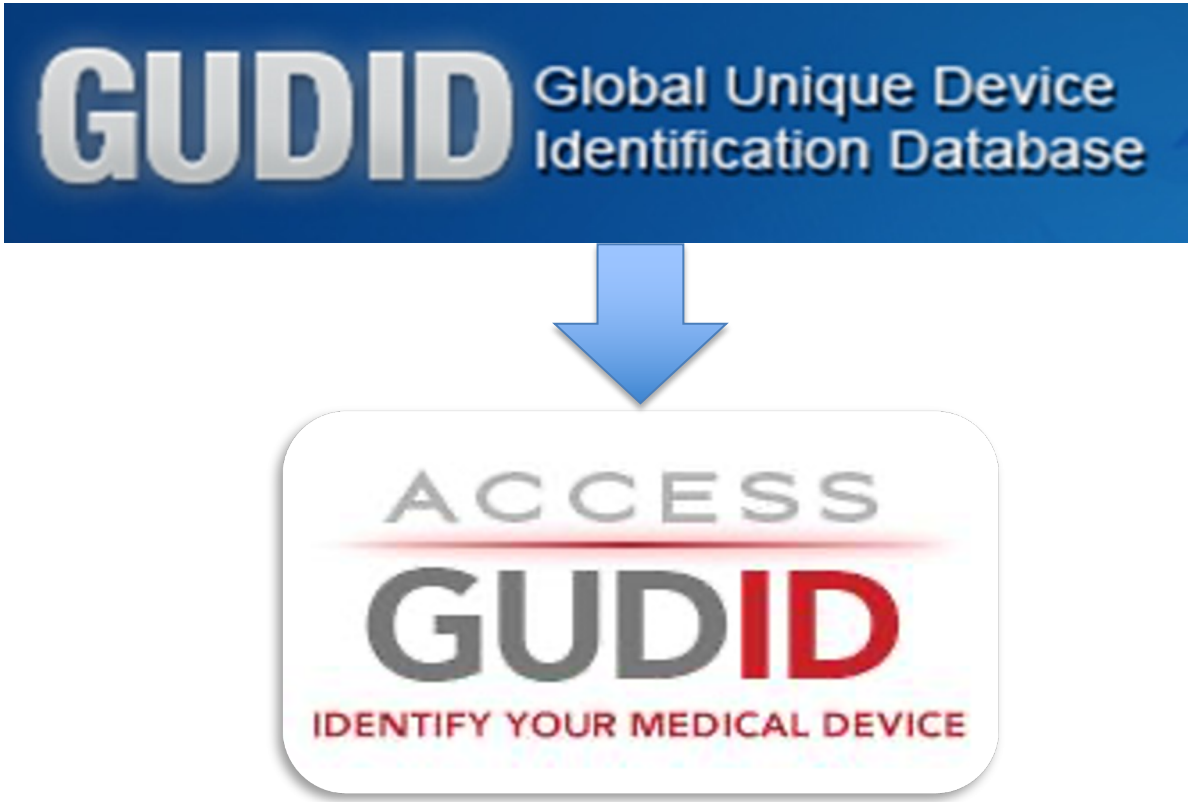
You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact UDI Regulatory Policy Support, 301-796-5995; email: GUDIDSupport@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Data Submission



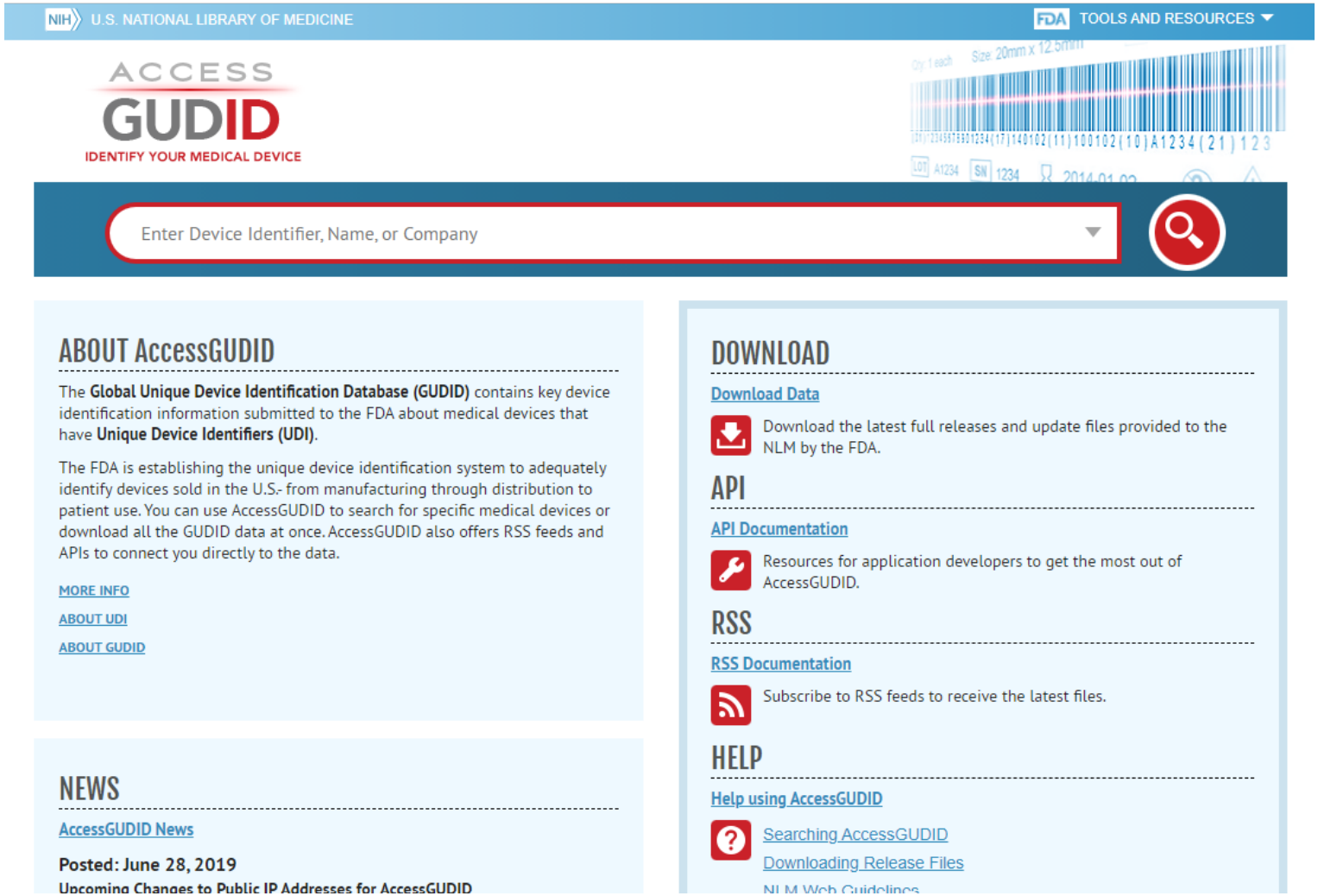
Data Use

Reference device identification information

Submit once – reuse in downstream systems

Optimize data quality based upon use

AccessGUDID



https://accessgudid.nlm.nih.gov/

FDA UDI Help Desk

GUDIDSupport@fda.hhs.gov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