

Regulación de UDI de la U.S. FDA y Actualizaciones Recientes

LCDR Michael Simpson, USPHS
UDI Project Manager
Office of Regulatory Programs
Center for Devices and Radiological Health
U.S. Food and Drug Administration

20 de enero, 2022

Establecimiento de un Sistema de UDI

*Reglamento
final de UDI*

[78 FR 58786]

24 sep 2013

Desarrollar un sistema normalizado para crear UDI

Colocar UDI en la etiqueta y (en algunos casos) el dispositivo

Crear y mantener una base de datos global de UDI

Adopción e implementación

Identificador Único de Dispositivo (UDI)

UDI = DI + PI

Qty: 1 each

Size: 20mm x 12.5mm

REF Z1234



(01)12345678901234 (17)140102(11)100102(10)A1234(21)1234



2014-01-02



2010-01-02

LOT

A1234

SN

1234



*+X999123ABC0

/\$\$3140102A1234/S1234/16D20100102J*

GS1

HIBCC



Manufacturer

CompuHyper GlobalMed, LTD

101 Innovation Drive,
New Sales, MD 20999-0000

XXX-867-5309 (USA)

XXX-555-3226 (Outside USA)

<http://www.compuhypergm.com>



=/A9999XYZ100T0479

=,000025=A99971412345600=>016008

ICCBBA

Cronología de la Implementación

	Fecha	Debe llevar el UDI y enviar información a la GUDID	Marcado Directo (para determinados usos)
	Sep 24, 2014	Dispositivos Clase III Dispositivos licenciados bajo la Ley de Servicio de Salud Pública (PHS)	
	Sep 24, 2015	Dispositivos implantable, para soporte de vida y mantenimiento (I/LS/LS)	Dispositivos LS/LS
	Sep 24, 2016	Dispositivos Clase II (no I/LS/LS)	Dispositivos Clase III y dispositivos licenciados bajo la Ley PHS
	Sep 24, 2018	Dispositivos Clase I Dispositivos no clasificados (no I/LS/LS)	Dispositivos Clase II (no LS/LS)
	Sep 24, 2020	Dispositivos Clase I Dispositivos no clasificados (no I/LS/LS)	Dispositivos Clase I Dispositivos no clasificados (no LS/LS)
	Sep 24, 2022	Dispositivos Clase I Dispositivos no clasificados (no I/LS/LS)	Dispositivos Clase I Dispositivos no clasificados (no LS/LS)

Guía de 2018

Guía de 2020

Guía de 2018

Armonización Internacional



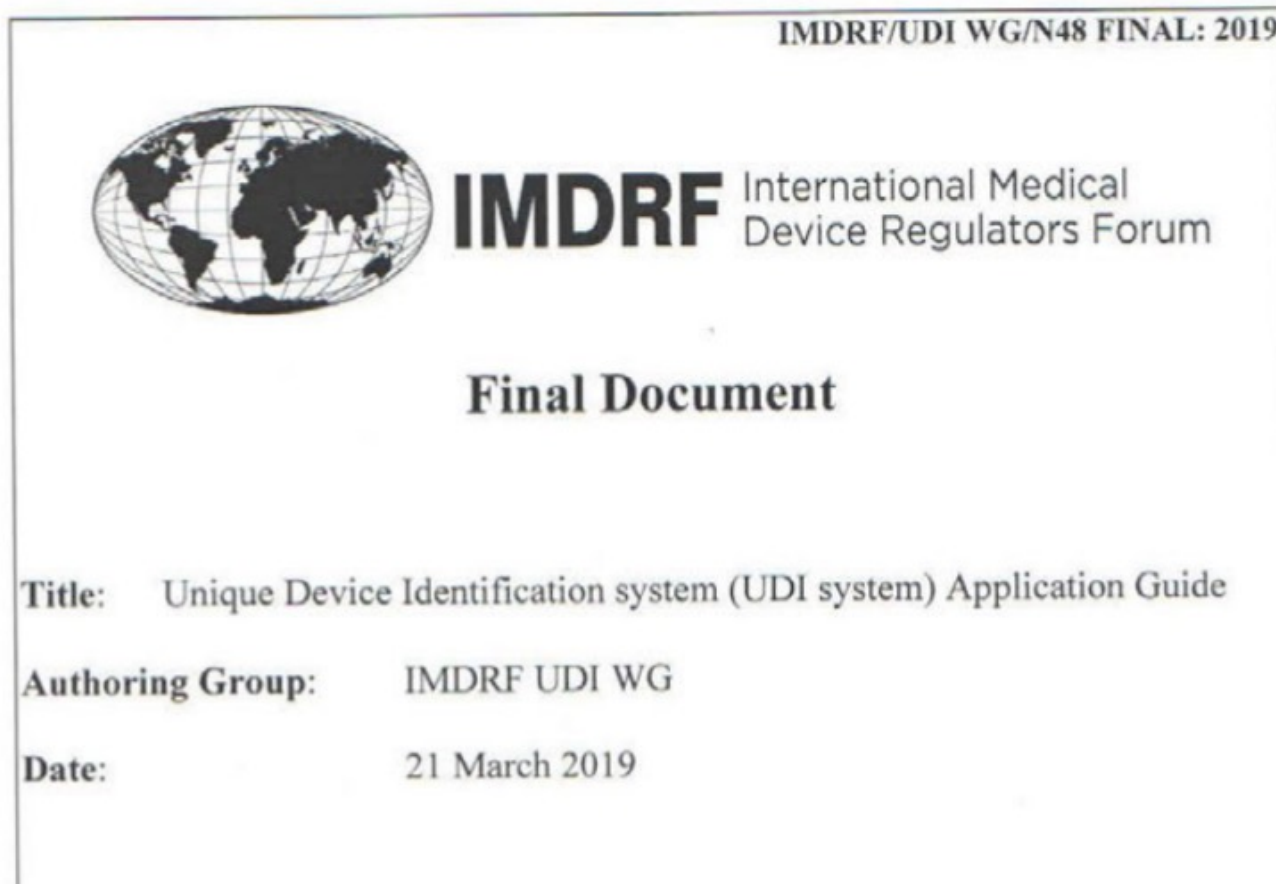
IMDRF/UDI WG/N7 Final: 2013

Guía para UDI

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

Guía para la Aplicación del Sistema de UDI



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/GlobalUIDatabase/GUID/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					Issuing 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

Requisitos del Sistema relacionado con el uso de UDI en los sistemas de salud, casos de uso seleccionados

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

UDI Rule and Guidances, Training, Resources, and Dockets

Subscribe to Email Updates

 Share

 Tweet

 LinkedIn

 Email

 Print

This page provides a comprehensive list of links to:

- [UDI rule and guidances](#)
- [UDI training for industry](#)
- [UDI and GUDID technical documents](#)
- [UDI dockets](#)

Guía Final sobre el formato y contenido del UDI



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

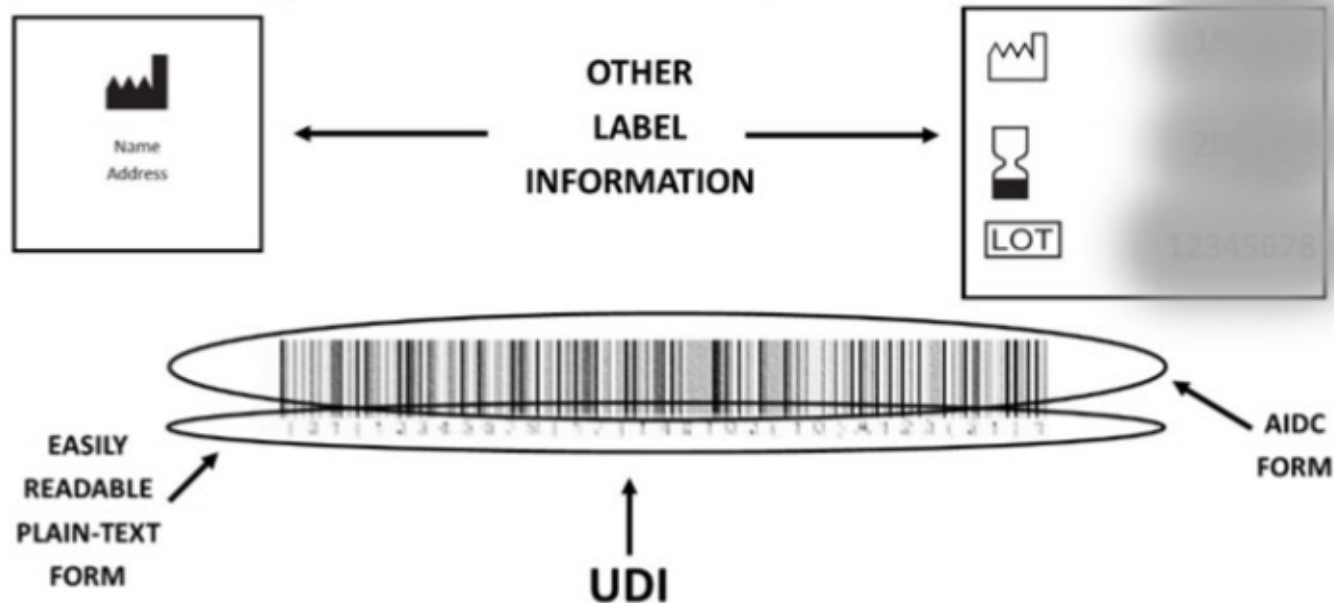


Figure 1. UDI in Easily Readable Plain-Text and AIDC Forms



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.



Presentación de Datos



Uso de los Datos

Información para la identificación del dispositivo de referencia
Presenta una vez – reutiliza en sistemas de niveles inferiores
Optimiza la calidad de la base de datos con base en el uso

AccessGUDID


U.S. NATIONAL LIBRARY OF MEDICINE


TOOLS AND RESOURCES ▼



IDENTIFY YOUR MEDICAL DEVICE





ABOUT AccessGUDID

The **Global Unique Device Identification Database (GUDID)** contains key device identification information submitted to the FDA about medical devices that have **Unique Device Identifiers (UDI)**.

The FDA is establishing the unique device identification system to adequately identify devices sold in the U.S.- from manufacturing through distribution to patient use. You can use AccessGUDID to search for specific medical devices or download all the GUDID data at once. AccessGUDID also offers RSS feeds and APIs to connect you directly to the data.

[MORE INFO](#)

[ABOUT UDI](#)

[ABOUT GUDID](#)

NEWS

[AccessGUDID News](#)

Posted: June 28, 2019

Upcoming Changes to Public IP Addresses for AccessGUDID

DOWNLOAD

[Download Data](#)

 Download the latest full releases and update files provided to the NLM by the FDA.

API

[API Documentation](#)

 Resources for application developers to get the most out of AccessGUDID.

RSS

[RSS Documentation](#)

 Subscribe to RSS feeds to receive the latest files.

HELP

[Help using AccessGUDID](#)

 [Searching AccessGUDID](#)

[Downloading Release Files](#)

[NLM Web Guidelines](#)

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

FDA UDI Help Desk

GUDIDSupport@fda.hhs.gov

