Global Unique Device Identification (UDI) Update

Including FDA Letters for "Devices Not in GUDID" and EU Legacy Device Extension

2023-Jun-29

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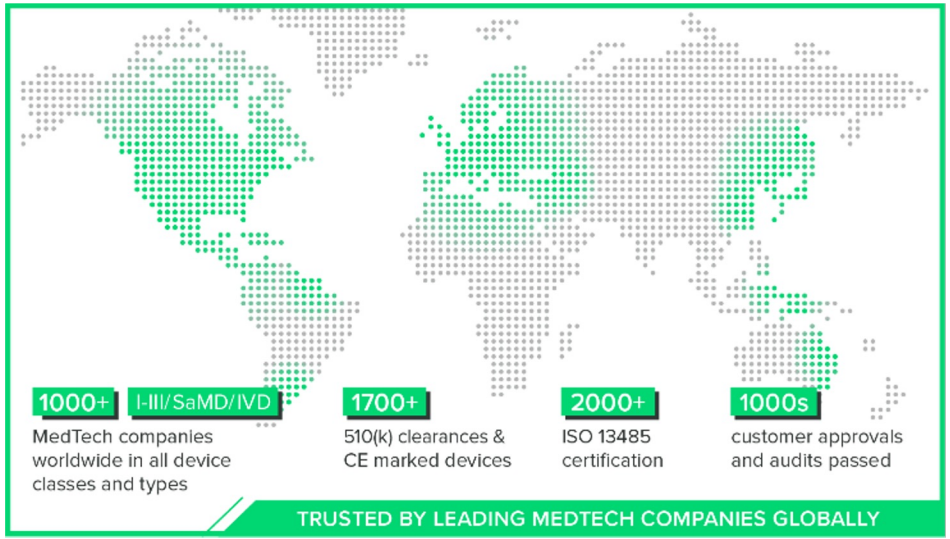

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Medical Device Guru,
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Reed Tech

Discussion Topics

- Global UDI Landscape
- US FDA UDI Hot Topics
- EU MDR/IVDR and UDI Update
- ROW UDI Summary
- QnA

Global UDI Landscape

What is UDI?

Unique Device Identification (UDI) Definition

- Globally unique, unambiguous, alphanumeric product identifier
- Assigned to a specific medical device model and version
- Comprised of a **Device Identifier** (DI) and a **Production Identifier** (PI)
- Created by…
- Applied to…
- Reported to…
- Used…
- Tracked…

Detailed definition in Appendix

Reference: FDA and other HAs; GS1 UDI Example

What are the UDI Components?

The UDI code consists of two parts:

Device Identifier (DI)

Mandatory, fixed portion that identifies the labeler and the specific version or model of a device

00855361005016

Production Identifier (PI)*

Conditional, variable portion that identifies one or more of the following when included on a device label:

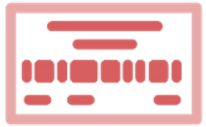
Manufactured Date	*2014-09-24*
Expiration Date	*2019-09-24*
Lot or Batch Number	*B35*
Serial Number	*S123*

UDI = DI + PI

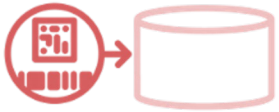
(01)00855361005016(11)140924(17)190924(10)B35(21)S123

* FDA adds DIN; EU Mfg conditional, adds Sfw ID

What are the UDI Requirements?



Apply UDI barcode and text
on Product and Package Labels



Report UDI Data to
Health Authority Database

Direct Mark UDI on
some Reused Products

Include UDI in SOPs,
Reports, and Records

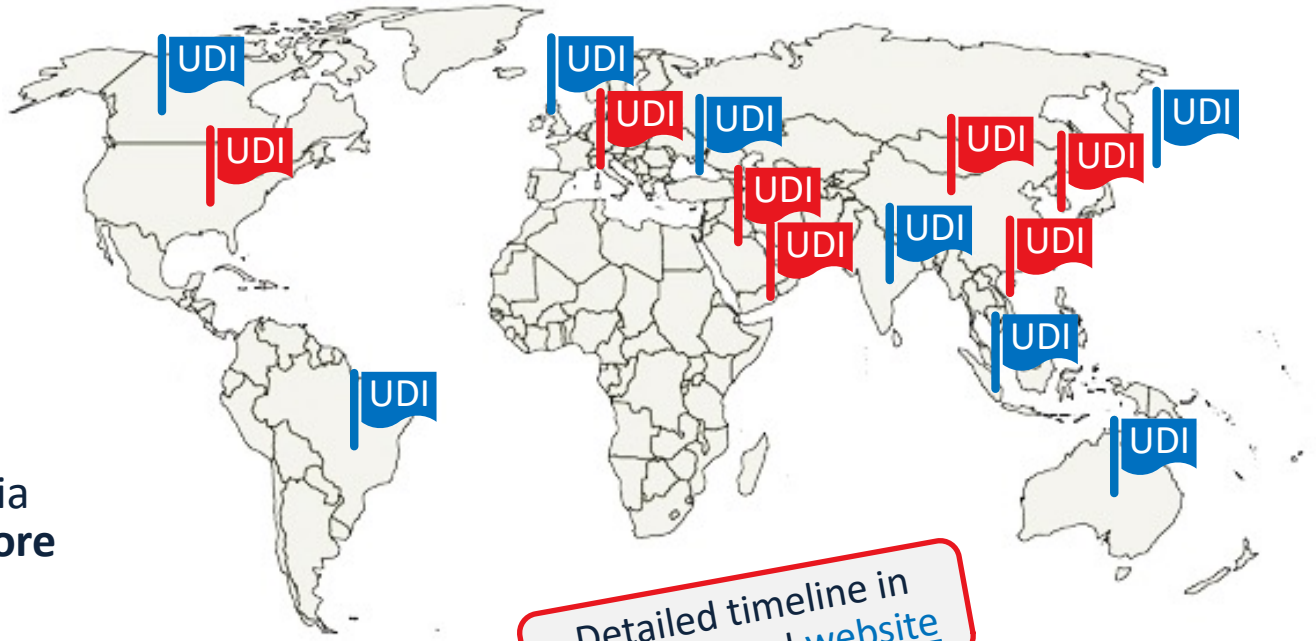
What Health Authorities Are Adopting UDI?

Active

- **U.S.** (2014)
- **EU** (2021/2022)
- **South Korea** (2019)
- **Netherlands** (2020)
- **UAE** (2020)
- **China** (2021)
- **Taiwan** (2021)
- **Saudi Arabia** (2023)

Pending

- **Australia**
- **Brazil**
- Canada
- India
- Japan
- Malaysia
- **Singapore**
- Turkey
- **UK**
- Other



Detailed timeline in Appendix and website

US FDA UDI Hot Topics

U.S. – FDA

Events

2013-Sep-24	Final Rule published
2022-Jul-25	GFI Class I Label due 2022-Sep-24, Class I GUDID due 2022-Dec-08, Class I OTC GUDID Exception

Compliance Timing

2014-Sep-24	Class III Devices
2015-Sep-24	I/LS/LS Devices
2016-Sep-24	Class II Devices
2022-Sep-24	Class I Devices (label, direct mark)
2022-Dec-08	Class I Devices (GUDID)

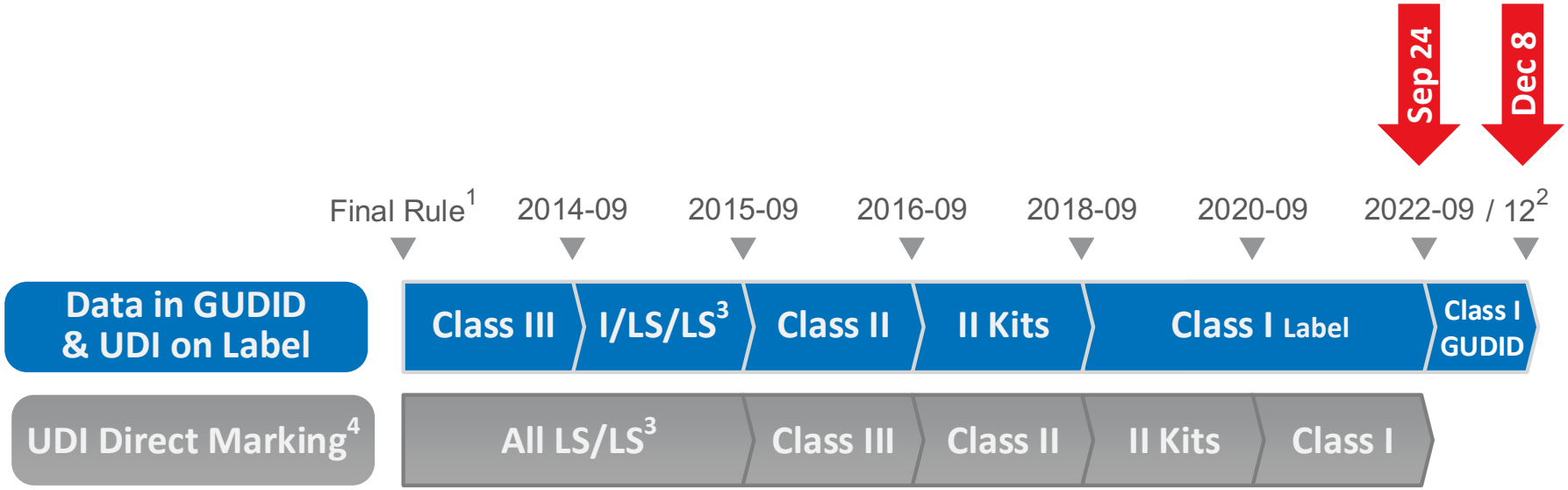
Description

- ***Approach*: UDI data reported & on labels by class; no change to device approval/registration**
- ***Database*: GUDID; functional; 3.9M records in public AccessGUDID**
- ***Data*: 57 reported attributes**
- ***Sub*: website entry or M2M SPL file via ESG**
- **Label:** HRI & AIDC; Direct Mark
- **STD:** GS1/HIBCC/ICCBBA; DUNS; GMDN/FDA
- **Info:** FDA UDI

I/LS/LS = Implantable, Life-Supporting, Life-Sustaining Devices; GFI = Guidance For Industry

FDA – Food and Drug Administration

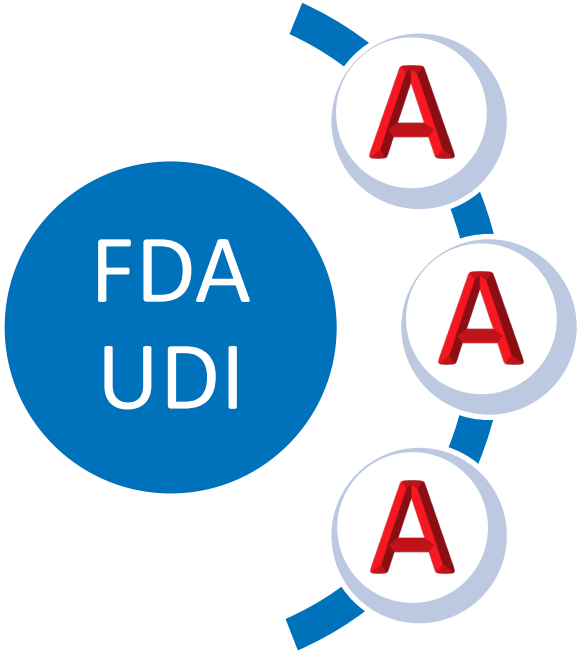
FDA UDI Compliance Timeline



1) FDA UDI Final Rule published 2013-09-24
2) Class I UDI Label and Direct Mark = 2022-09-24, GUDID Submission = 2022-12-08
3) I/LS/LS = Implantable, Life-supporting, and Life-sustaining devices
4) Direct Marking (DM) required if multiple patients and undergo high-level disinfection and/or sterilization between use

FDA Final Rule

FDA UDI Hot Topics



Administration and Enforcement of Regulations

- Letters to Mfrs with listed products not in GUDID
- GUDID data validation rules
- Inspection and Custom checks

Accuracy of GUDID Data

- Notice to update GMDN Codes
- Advice to enter Catalog #, Description, etc.
- Maintain current data (Pkg Level, End Dates, etc.)

Adoption by Industry

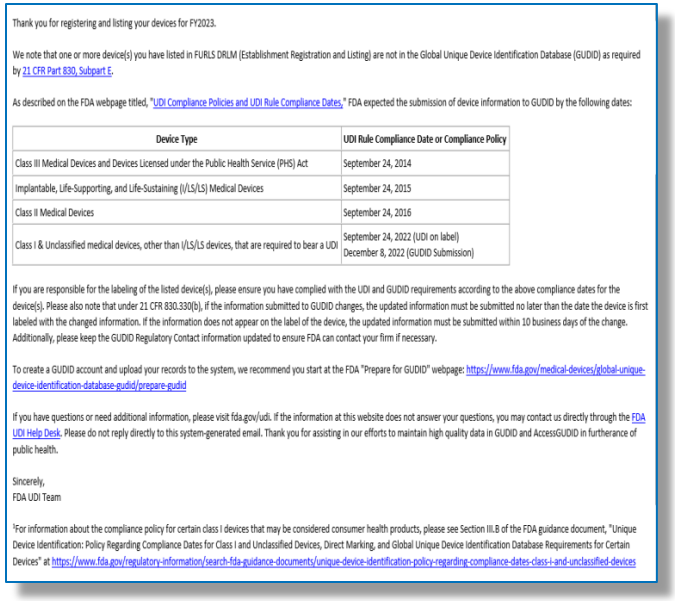
- Safety Reporting (Adverse Events, etc.)
- Supply Chain thru Healthcare Providers

2022-Nov FDA plans to increase UDI enforcement

FDA Letter: Missing GUDID Products

Letter:

- @ June 7, 2023, FDA initiated a GUDID quality campaign
- If the FDA review of the FDA Unified Registration and Listing System (FURLS) database discovered products that are listed, but not in the GUDID, the FDA emailed those organizations notifying them of the omission
- FDA expects organizations to comply with UDI regulations including UDI labeling and GUDID reporting as necessary and within the now past deadlines



Thank you for registering and listing your devices for FY2023.

We note that one or more device(s) you have listed in FURLS DRLM (Establishment Registration and Listing) are not in the Global Unique Device Identification Database (GUDID) as required by 21 CFR Part 830, Subpart E.

As described on the FDA webpage titled, "UDI Compliance Policies and UDI Rule Compliance Dates," FDA expected the submission of device information to GUDID by the following dates:

Device Type	UDI Rule Compliance Date or Compliance Policy
Class III Medical Devices and Devices Licensed under the Public Health Service (PHS) Act	September 24, 2014
Implantable, Life-Supporting, and Life-Sustaining (I/LS/LS) Medical Devices	September 24, 2015
Class II Medical Devices	September 24, 2016
Class I & Unclassified medical devices, other than I/LS/LS devices, that are required to bear a UDI	September 24, 2022 (UDI on label) December 8, 2022 (GUDID Submission)

If you are responsible for the labeling of the listed device(s), please ensure you have complied with the UDI and GUDID requirements according to the above compliance dates for the device(s). Please also note that under 21 CFR 830.330(b), if the information submitted to GUDID changes, the updated information must be submitted no later than the date the device is first labeled with the changed information. If the information does not appear on the label of the device, the updated information must be submitted within 10 business days of the change. Additionally, please keep the GUDID Regulatory Contact information updated to ensure FDA can contact your firm if necessary.

To create a GUDID account and upload your records to the system, we recommend you start at the FDA "Prepare for GUDID" webpage: https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/prepare-gudid

If you have questions or need additional information, please visit fda.gov/udi. If the information at this website does not answer your questions, you may contact us directly through the FDA UDI Help Desk. Please do not reply directly to this system-generated email. Thank you for assisting in our efforts to maintain high quality data in GUDID and AccessGUDID in furtherance of public health.

Sincerely,
FDA UDI Team

[1]For information about the compliance policy for certain class I devices that may be considered consumer health products, please see Section III.B of the FDA guidance document, "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" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices

FDA Letter: Missing GUDID Products (2)

Action:

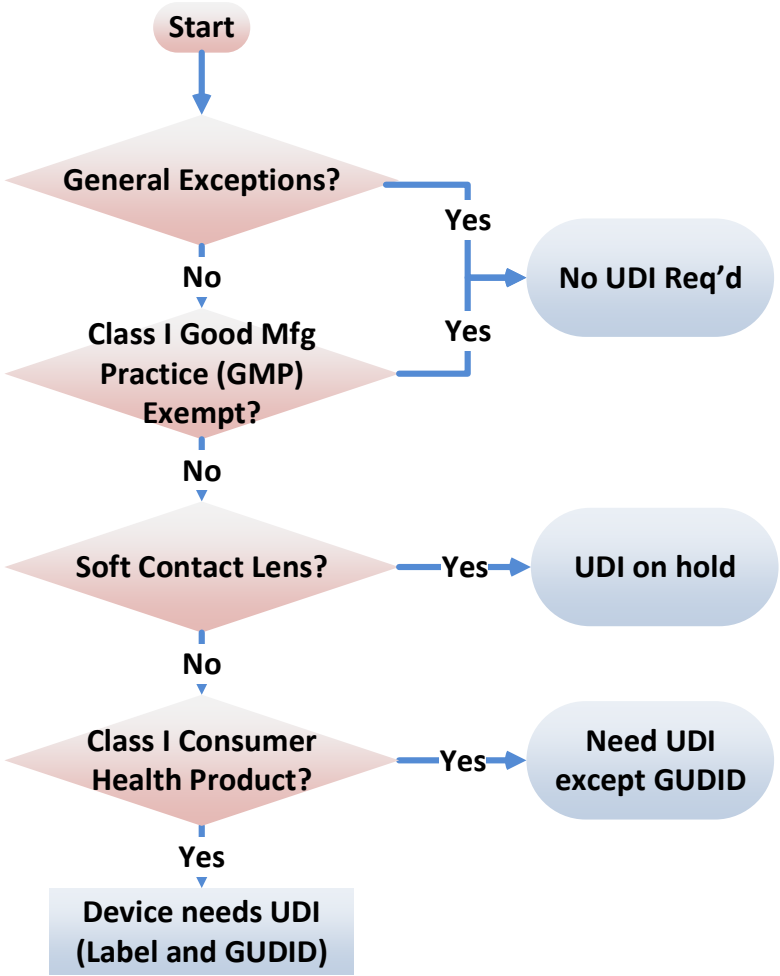
1. Promptly evaluate your listed products in FURLS and determine why any device is not in the GUDID

2. If a device is excepted from UDI labeling and/or GUDID reporting:
   Document such in your Design History File (DHF)

3. If a device is delinquent in being reported to GUDID:
   Complete any necessary UDI compliance activities, e.g., UDI labeling and GUDID reporting, **as soon as possible.** You must comply with FDA UDI regulations and past deadlines, see UDI website

4. Consider voluntary UDI submissions
   Consider voluntary response to FDA UDI Help Desk

FDA UDI Flowchart



General Exceptions

- Field Device
- Research Device
- Custom Device
- Investigational Device
- Veterinary Medical Device
- U.S. Export
- National Stockpile Device
- Device in Convenience Kit or Combo Product(?)
- Consignment Inventory
- Bulk Single Use Device(?)
- Not classified (Unclassified needs UDI)
- Rx Spectacle Lens (HQG)

Soft Contact Lenses

(LPM, NCZ, NIC, LPL, MVN)

Class I Consumer Health Product

(510 Exempt & sold only in OTC/retail)

FDA Notice: GMDN Codes in GUDID

Notice:

- @ June 7, 2023, FDA published a notice on the GUDID website and sent emails
- FDA to include the Global Medical Device Nomenclature (GMDN) Term Codes and Status (active/obsolete) on the public AccessGUDID database as of August 14, 2023.
- Labeler to update GMDN codes by **July 31, 2023**.

FDA to update AccessGUDID Database and OpenFDA

On August 14, 2023, the U.S. Food and Drug Administration (FDA) will update the fields released in the public AccessGUDID Database and the openFDA Unique Device Identifier endpoint to include Global Medical Device Nomenclature (GMDN) Term Codes along with the status of the GMDN Term Code, Active or Obsolete. If a labeler submitted an FDA Preferred Term (FDA PT) Code to meet their GMDN Code data entry requirement, the equivalent GMDN Code will now also be released publicly. This latest update is intended to provide end users with enhanced search and retrieval capabilities for GUDID data.

To prepare for this upcoming release, the FDA is reminding labelers to review their GUDID records to assure their GMDN Term Code or FDA PT Code assignment is correct, and the code is active, NOT obsolete, consistent with labelers' obligation to update the information they have submitted to GUDID in 21 CFR 830.330(b). The FDA expects labelers to complete their updates within the timelines specified in the regulations and by the end of July 2023 to assure accurate information is released in GUDID and openFDA.

GUDID Database

Resources are available on the GMDN website to help labelers identify alternatives to obsolete term codes.

Questions?

If you have questions or need further assisstance, please contact the FDA UDI Help Desk.

GMDN Code	Status	GMDN Preferred Term Name	GMDN Definition
47569	Active/ Obsolete	Scalpel, single-use	A hand-held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device.

FDA Notice: GMDN Codes in GUDID (2)

Action:

1. All labelers should promptly check their reported GMDN and FDA PT (Preferred Term) codes
   - GMDN codes (5-digits) can be verified through a GMDN subscription service
   - FDA PT (Preferred Term) codes (4-letters) can be verified using the FDA GUDID web interface
2. If changes are required, e.g., replace an obsolete code, correct a code, submit an updated UDI record to the FDA GUDID on or before **July 31, 2023**.

FDA GUDID Record Maintenance/New Entry

FDA GUDID Submission Timing of New/Updated/Retired Records

Event	Activity	GUDID Publication Time Requirement
Existing Product (initial report)	New[1] Record	**Prior** to Compliance Date [2]
New Product or New Model/Version	New[1] Record	After Compliance Date, publish within **15** calendar days after initial commercial distribution [3]
Label Attribute Change (e.g., Catalog Number)	Update Record	**Prior** to commercial distribution [2]
Non-Label Attribute Change (e.g., GMDN Code)	Update Record	Within **10** business days after commercial distribution [2]
FDA Notification of Error	Update Record	Correct GUDID record or respond with explanation within **30** days after notification [4]
Retire Device (stop commercial distribution)	Update Record	Publish "Distribution End Date" [2] and store data for **3** additional years

(1) For new SPL submission, "publish" = receive successful ACK 3 message; FDA has a 7-day (previously 30d) Grace Period before updating AccessGUDID; (2) eCFR 830.330 UDI Submission Times, (3) FDA GFI: GUDID Database; (4) eCFR 830.350 UDI Correction Time

Poll Question #1

EU MDR/IVDR and UDI Update

EU – EC

Events

2021-May-26	MDR DoA
2022-May-26	IVDR DoA
2024-Q2	EUDAMED “Functional” Notice (6 modules fully functional)

Compliance Timing

2020-Dec-01	Actor Vol Registration
2021-May-26	MDR Class I Self-cert req’d
2021-Oct-04	UDI/Device & Cert/NB Vol Reg
2022-May-26	IVDR Class A Self-cert req’d
2024-Q4	Legacy, MD, IVD: UDI/Device Reg Mandate Start (notice+6m)
2026-Q2	Legacy, MD, IVD: UDI/Device Registration Deadline (notice+24m)

Description

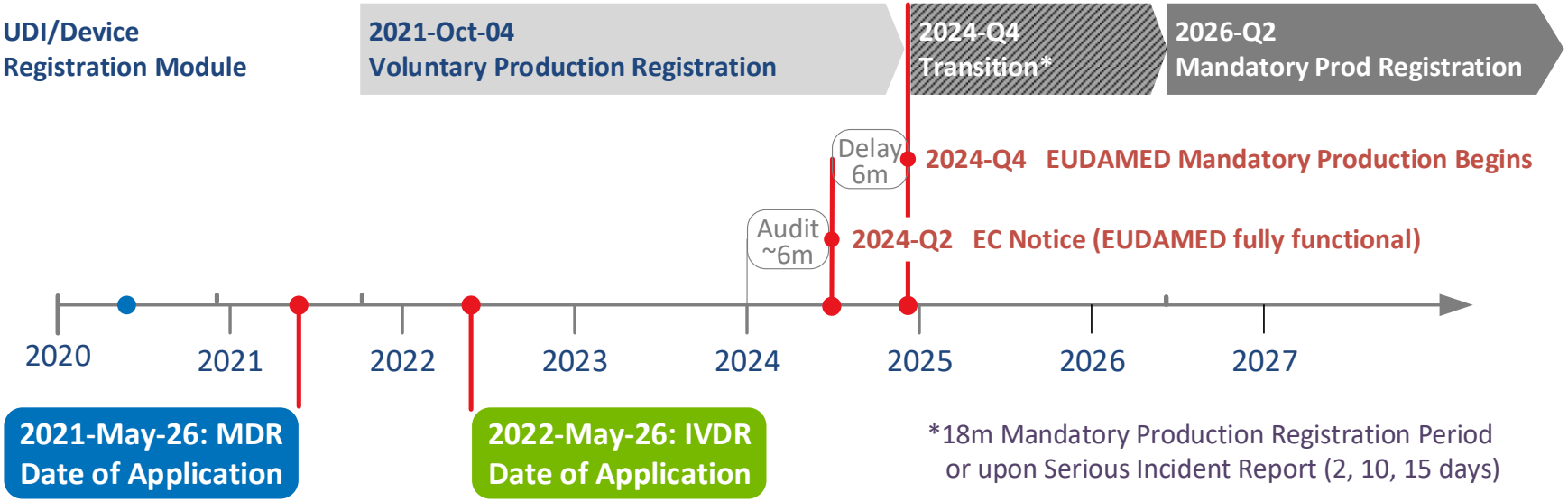
- ***Approach***: **new regulations** for approval, reg, UDI data/labels, vigilance, etc.; rules & timing for Legacy Directive, MDR, IVDR devices
- ***Database***: EUDAMED 3 modules open (Actor, UDI, Cert); 3 future (Vigilance, CI, Mkt Suv)
- ***Data***: 111 attributes; new **BUDI-DI** “device group” concept
- ***Sub***: website entry/XML upload or M2M XML transfer via Data Exchange (DTX)
- ***Label***: HRI & AIDC by class (2021,2023,2025) Direct Mark by class (Label + 2y)
- ***STD***: GS1/HIBCC/ICCBBA/**IFA**; **SRN**; **EMDN** (CND)
- ***Info***: EC Reg, UDI

EC – European Commission

What is Unique About the EU UDI?

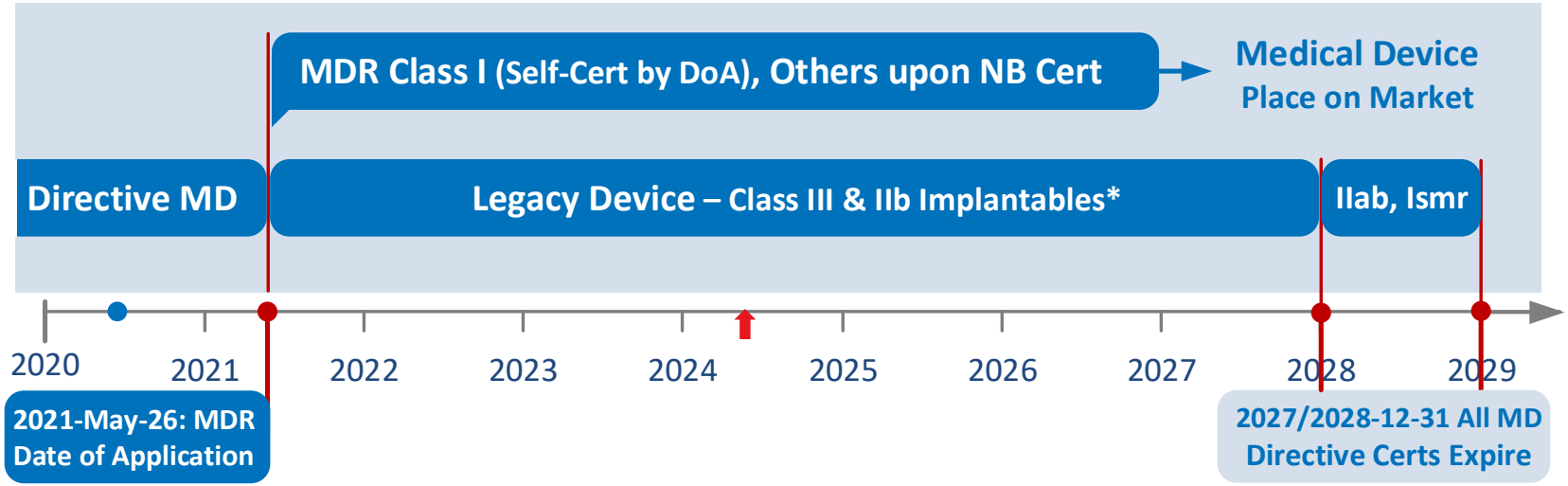
- **New Regulatory Framework**
  - MDR/IVDR replace Directives
  - All NBs new designation (no grandfathering)
  - All Products new certification (no grandfathering)
  - UDI policy is similar, but different than US
- **New Concepts**
  - Directive, Legacy, Equivalent/Replacement, MDR/IVDR compliant devices
  - Basic UDI-DI (group) and UDI-DI (device) identifiers, (and Master DI)
  - More UDI Data (2x), SRN, EMDN, IFA, etc.
- **Confusing Timing**
  - Place on market, registration, UDI labels, UDI Direct Marking all scheduled differently
  - EUDAMED – Actor and UDI Device modules open now for voluntary registration
  - 2024-Q4 to 2026-Q2 Mandatory UDI/Device Registration

EUDAMED Timeline



Detailed timeline in Appendix

EU MDR/IVDR Timeline



Detailed timeline in Appendix

* Except WET: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

EU Amend MD Legacy Transition Extension

Notice: 2023-03-20 EU Regulation 2023/607

Summary: EU Amendment on **MD Legacy Transition Extension** includes:

- Extend transition period to place Legacy devices on the market from 2024-May-26 to:
  - **2027-Dec-31** (+3yr 7m) for **Class III and IIb Implantables** (excludes Well-Established Technology*)
  - **2028-Dec-31** (+4yr 7m) for **Class IIb Implantables*, IIb non-Implantables, IIa, and Ismr****, and **up-classified "1st certificate" devices**
- Extend the validity of Legacy MDD and AIMDD certificates to above dates [MDR Article 120(2)]
- Extend QMS certification deadline to 2026-May-26 for Class III custom-made Implantables
- Remove 1-year "**Sell-off**" limit for Legacy MD (and IVD) devices to flow through supply chain

* sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

** Ismr = Class I Sterile, Measuring Function, and Reusable Surgical Instrument

EU Amend MD Legacy Transition Extension

Notice: 2023-03-20 EU Regulation 2023/607

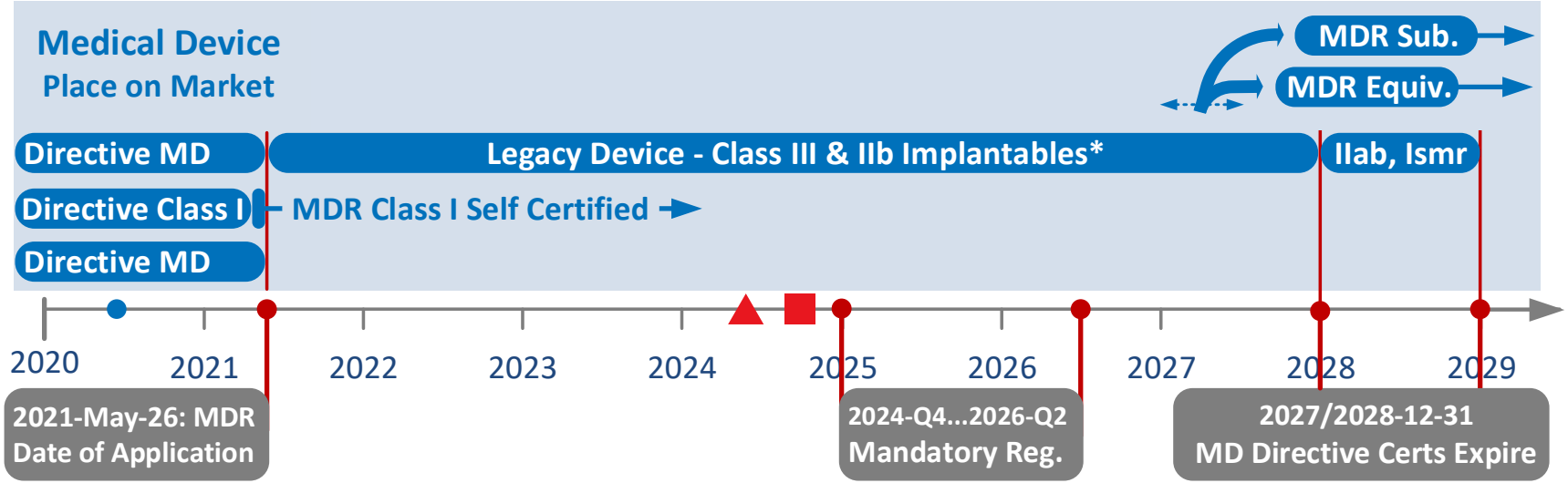
Criteria: Limited to Legacy Devices that meet the following:

- Valid certificate (or Declaration of Conformity) as of 2021-May-26 (DoA); Certificate is not withdrawn
- Complies with Directives; Follows MDR Post-mkt Surv, Mkt Surv, Vigilance, Registration of Econ Oper & Devices
- **No significant changes in design or intended purpose**; Does not present an unacceptable risk to health & safety
- NB MDR assessment agreement before expiry or derogation/assessment procedures per MS
- **MDR QMS installed by 2024-May-26**
- **NB MDR assessment applied for by 2024-May-26** [Basic DI & UDI-DI assigned] and **signed by 2024-Sep-26**

* sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

** Ismr = Class I Sterile, Measuring Function, and Reusable Surgical Instrument

Legacy Device – Timeline



▲ = 2024-May-26 QMS installed, NB MDR assessment requested (Basic-DI & DI assigned), (Previous Legacy MD deadline)

■ = 2024-Sep-26 NB MDR assessment signed

* Except WET: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

Poll Question #2

ROW UDI Summary

More Health Authority notecards on website

Australia – TGA

Events

2019-Jan-07	UDI System Proposal
2019-Apr-04	UDI Action Plan
2020-Sep-23	UDI Consultation Survey
2021-Feb-19	Therapeutic Goods Amend
2022-Aug-31	UDI Consultation #3
2023-Dec?	Regulations & Guidance

Compliance Timing

2022-Jul-04	**AusUDID Sandpit** (test, general use)
2023-Dec?	Vol Labeling/Data
2024-Dec?	Req'd Labeling/Data (MD III, IIb)
2025-Dec?	Req'd Labeling/Data (MD IIa)
2026-Dec?	Req'd Labeling/Data (MD Is, IVD 4,3,2)
2027-Dec?	Req'd Labeling/Data (IVD 1)

Description

- ***Approach***: device UDI data/labels by class; based on IMDF, US, and EU; usage fee
- ***Database***: **AusUDID** link to ARTG
- ***Data***: 71 attributes; similar to US (+ **BUDI-DI)**
- ***Sub***: website entry or XLS file upload or bulk M2M (SPL) or bulk NPC (GDSN)
- ***Label***: HRI & AIDC (1D or 2D), Direct Mark (DM); accept EU & US labels(?)
- ***STD***: GS1, HIBCC, ICCBBA; GMDN, EMDN, INMD
- ***Info***: TGA Medical Device & IVD, UDI

MD Class I voluntary
ARTG – Australian Register of Therapeutic Goods
NPC – National Product Catalogue

TGA – Therapeutic Goods Administration

China – NMPA

Events

2019-Jul-03	UDI Batch 1 pilot notice & guide
2019-Sep-17	Batch 1 Notice 2020-10-01 and list
2020-Sep-30	Batch 1 Notice delay 2021-Jan-01; 69 (64+5) categories
2021-Sep-26	Batch 2 Notice due 2022-Jun-01
2022-Nov-30	Batch 3 draft due 2024-Jun-01

Compliance Timing

2021-Jan-01	Batch 1 Few Class III data & label
2022-Jun-01	Batch 2 Remaining Class III
2024-Jun-01	Batch 3 Class II List
TBD (2026?)	Class I and Remaining

Description

- ***Approach***: device UDI data/labels; scheduled by "Batch" lists with high-risk classes first; early adoption by some Provinces and Hospitals
- ***Database***: UDID; 2.6+m items @2023-Feb
- ***Data***: 51 attributes; 37 similar to US (no BUDI)
- ***Sub***: website entry/file upload or M2M XML transfer via API; need local rep
- ***Label***: HRI & AIDC (1D or 2D barcode)
- ***STD***: Issuing Agencies: GS1 China, ZIIOT*, Ali Health Mashangfangxin Platform
- ***Info***: NMPA

NMPA – National Medical Products Administration

* Zhongguancun Industry & Information Research Institute of Two-Dimensional Code Technology

South Korea – MFDS

Events

2016-Dec	Medical Device Act revised (UDI)
2019-Jun	UDI System introduction

Compliance Timing

Date	UDI	Trace & Trace
2019-Jul-01	Class IV*	~~~
2020-Jul-01	Class III	Class IV**
2021-Jul-01	Class II	Class III
2022-Jul-01	Class I	Class II
2023-Jul-01	~~~	Class I

Description

- ***Approach***: device UDI data/labels by class; AND **Supply Report (Track & Trace)** of ~10 distribution metrics each month
- ***Database***: **IMDIS** (Integrated Medical Device Information System), no Pre-production
- ***Data***: 40 attributes; 15 auto populated by MFDS in initial XLS dnload; 15 similar to US (no BUDI)
- ***Sub***: website XLS download/complete data /upload file or M2M XML transfer via API
- ***Label***: HRI & AIDC, Direct Mark
- ***STD***: GS1, HIBCC, ICCBBA
- ***Info***: MFDS, IMDIS UDI System

* Report data by Oct ** Enforcement discretion to EOY 2020

MFDS – Ministry of Food and Drug Safety

Saudi Arabia – SFDA

Events

2019-2020	UDI Pilot
2020-Sep-06	Formal Guidance (V3) released
2020-Oct-01	UDI Database open (voluntary)
2021-Oct-26	UDI Compliance Dates delayed
2022-Jun-24	UDI Compliance Dates delayed

Compliance Timing

2023-Sep-01	Class D (high risk)
2023-Sep-01	Class B & C (medium risk)
2024-Sep-01	Class A (low risk)
+1 year	Direct Mark

Description

- ***Approach***: device UDI data/labels by class; (**Import and Track & Trace modules on hold**)
- ***Database***: **Saudi-DI**; functional
- ***Data***: 43 attributes; 29 similar to US (no BUDI)
- ***Sub***: website **manual entry only**: expect future XLS upload and M2M XML file transfer
- ***Label***: HRI & AIDC, Direct Mark
- ***STD***: GS1, HIBCC, ICCBBA
- ***Info***: SFDA

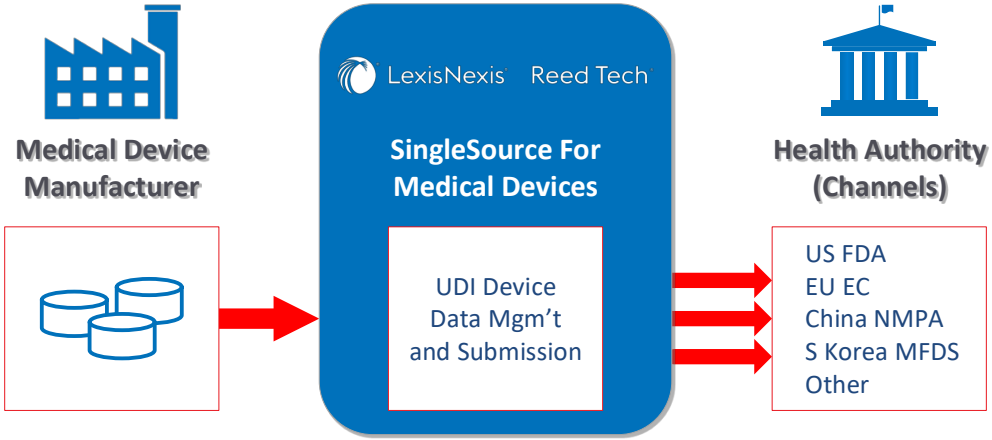
SFDA – Saudi Food and Drug Authority

Questions & Answers

Reed Tech SingleSource™ For Medical Devices

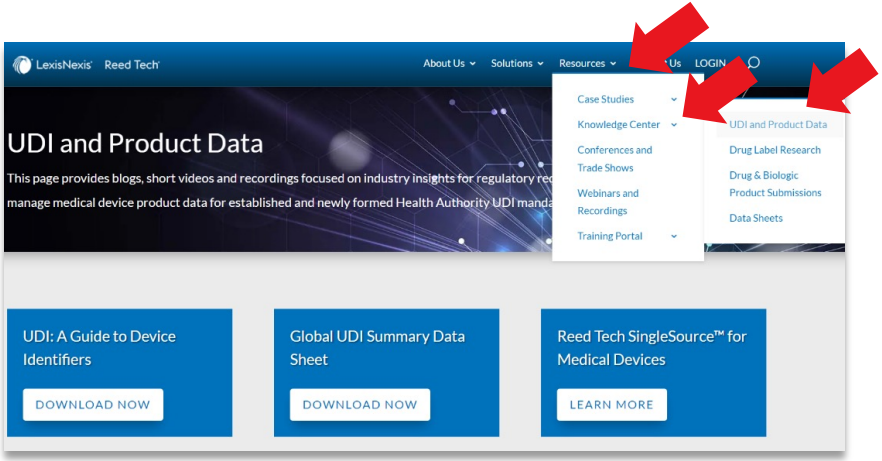
SingleSource enables Medical Device manufacturers to quickly react and affordably comply with business-critical product data submission requirements across the globe.

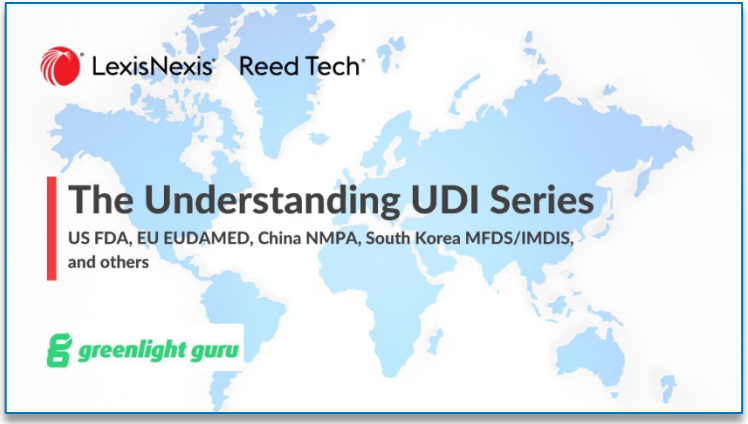
It provides a single, scalable, and flexible data management platform which allows users to collect, maintain, validate, and submit their product data to global health authorities and supply chain partners.



More Information

ReedTech.com > Resources > Knowledge-Center > UDI and Product Data





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Thank you !

Appendix

What is UDI?

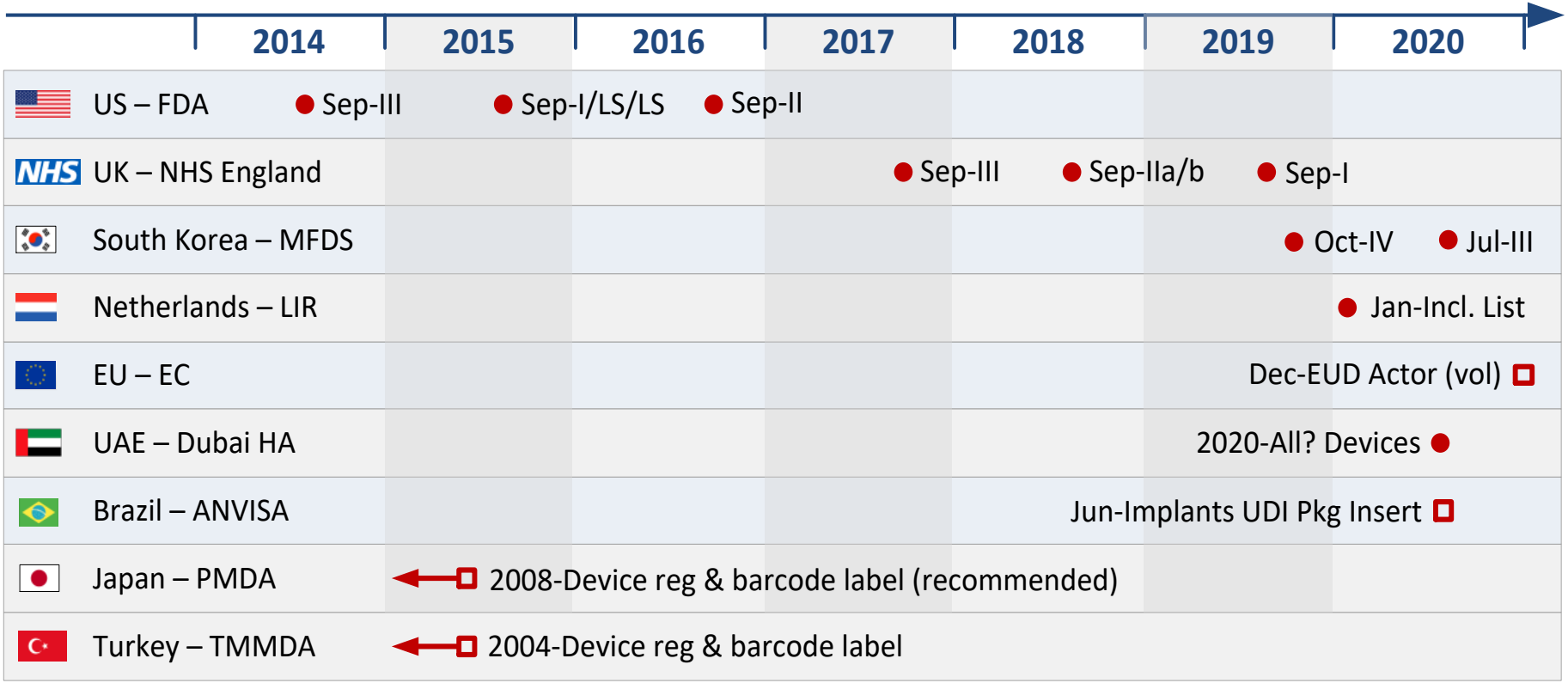
Unique Device Identification (UDI) Definition

- Globally unique, unambiguous, alphanumeric product identifier
- Assigned to a specific medical device model and version
- Comprised of a **Device Identifier** (DI) and a **Production Identifier** (PI)
- Created by the product owner per a Health Authority-approved Issuing Agency standard
- Applied to the product and package labels in human- and machine-readable form
- Reported to Health Authority product registration and surveillance repositories
- Used through lifecycle from manufacturer, supply chain distributor, provider, to end user
- Tracked in industry public and private databases, registries, EHR, claims, etc.

Reference: FDA and other HAs

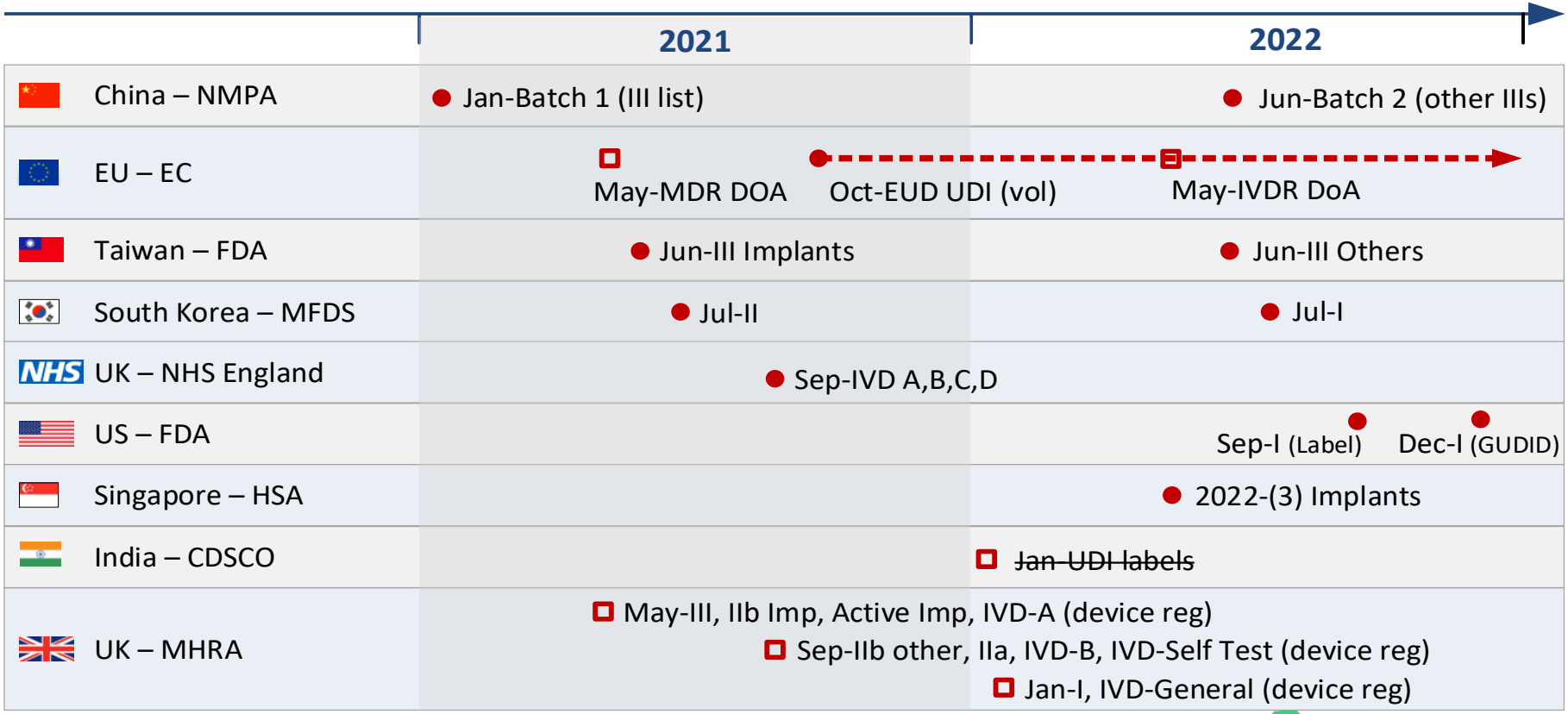
GS1 UDI example

Early UDI Data Reporting Reqm'ts



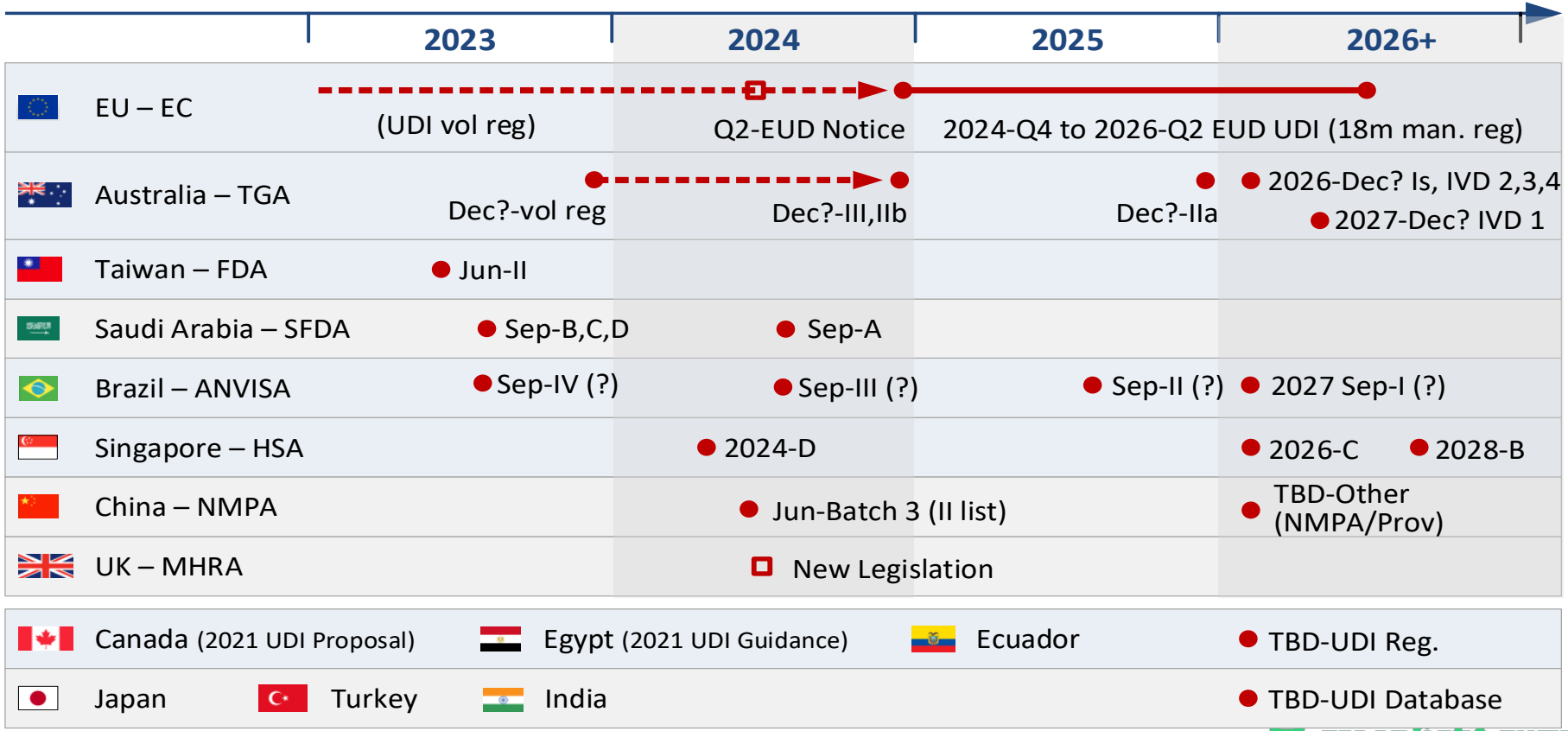
● UDI Submission Deadline, ☐ Milestone

Recent UDI Data Reporting Reqm’ts



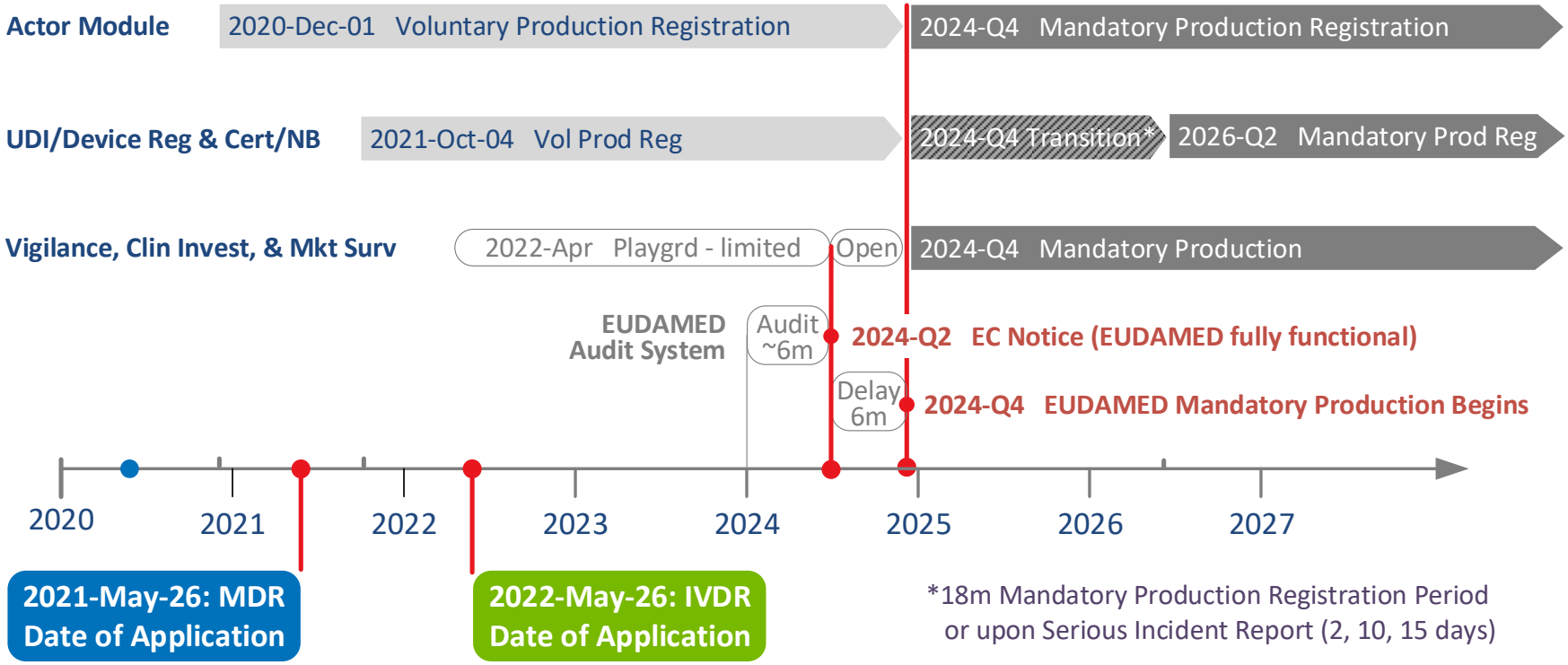
● UDI Submission Deadline, ☐ Milestone

Future UDI Data Reporting Reqm’ts



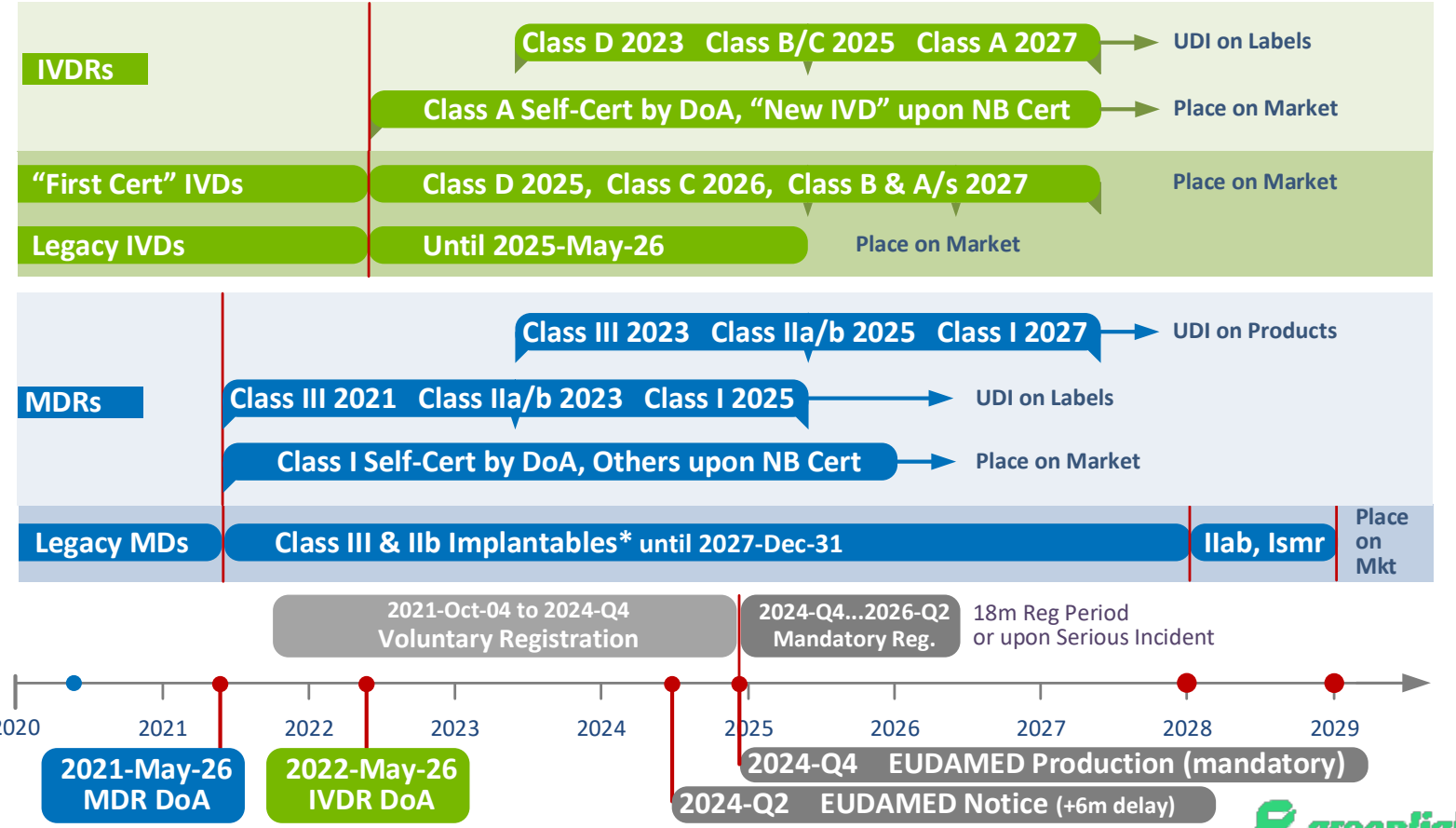
● UDI Submission Deadline, □ Milestone

EUDAMED Timeline



*18m Mandatory Production Registration Period or upon Serious Incident Report (2, 10, 15 days)

EU MDR/IVDR Timeline



* Except WET: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

2023-03-20 OJEU publish MD Legacy Amend 2023/607

Reed Tech SingleSource™ - EU Implementation Plan

LexisNexis® Reed Tech®

WHEN

Q4 2023	Q1-Q2 2024	Q2 2024	Q4 2024	Q2 2026
End EUDAMED MVP Dev-6 Modules	Audit EUDAMED	Full functionality expected EUDAMED	Mandatory use expected EUDAMED-Actors, Vigilance, Clinical Investigation & Performance Studies and Market Surveillance Modules	Mandatory use expected UDI/Device and NB & Certificate Modules

WHAT

REGISTER
in EUDAMED Actor Module

ONBOARD
Reed Tech UDI
- Dataset
- Template
- UDI System

SETUP
EUDAMED UDI
- Module
- Account

ESTABLISH
- Internal SOPs
- Roles

ASSIGN
Product UDIs, BUDI-DIs
- Collect
- Import
- Cleanse

BUILD
(if applicable) optional M2M interface to SingleSource

INTERFACE
- Test
- Validate submissions

SUBMIT
Submit product data to EUDAMED

Variables:
- Available resources
- Subject-matter expertise
- Infrastructure complexities
- Data scattered across multiple locales/formats

HOW

2-6 months

Create UDI Environment

Collect UDI Data

1-2 months

Cleanse UDI Data

Comply with Regulations

greenlight guru

EU Legacy Registration – Early

There are good business reasons to register Legacy devices early:

1. Legacy devices (or the Equivalent MDR device) will eventually have to be registered in EUDAMED.
2. Legacy devices have Directive information, Directive certificates if required, and other attributes currently available for submission now. MDR devices typically have a longer preparation runway, e.g., they need new MDR documentation, technical reviews, and all certificate devices also need NB MDR evaluation (NBs are overbooked causing delays).
3. Early registration of “ready-to-go” Legacy devices avoids the expected heavy workload/rush by manufacturers, NBs, and EC to register MDR devices later on.
4. Early registration establishes and exercises the EUDAMED submission process.
5. 99% of all devices in the marketplace are Legacy devices, so any serious events that need to be reported as of 2023-Q4 will require prior registration of the Legacy device (or the Equivalent MDR device if it is already certified). Early Legacy device registration avoids the panic perquisite registration of 2, 10, or 15 days.

EU Legacy Registration – Late

There are some Technical/Business reasons not to register Legacy devices too early:

1. The EUDAMED launch date has been delayed multiple times; it is possible the launch may be delayed again.
2. EUDAMED UDI module still has some features and fixes to implement (avoid the “bleeding edge”); record updates may be required.
3. Early production registration is subject to EUDAMED record maintenance and new DI trigger rules (still subject to revision).
4. Legacy devices that have an Equivalent MDR device only need one record submission (the Equivalent MDR device), so as time marches on and more Equivalent MDR devices are ready, one record is required instead of two records (one early Legacy record and one later for the Equivalent MDR record).

Each manufacturer needs to consider the submission timing options for Legacy and MDR devices and plan an approach that best suits their business. In all cases, it is prudent to start the data collecting/cleansing process early.