

Enabling Effective UDI Systems:

Industry Recommendations for Practical Implementation, Traceability and Alignment

Position Paper

REGULATORY AFFAIRS

Table of Contents

Executive Summary	3
1. Glossary	4
2. Introduction	4
3. Current UDI Landscape	5
4. Principles for Effective UDI Implementation	6
5. Common Pitfalls to Avoid	7
6. Considerations for Authorities Designing or Revising UDI Systems	8
6.1 Pre-Implementation Readiness: Checklist for Authorities	8
6.2 Considerations for Effective UDI Systems	9
6.2.1 Align with Global Standards	10
6.2.2 Regulatory scope & strategy	10
6.2.3 Stakeholder Engagement and Ecosystem Readiness	12
6.2.4 Scalable and Interoperable UDI Infrastructure	13
6.2.5 Data Governance and Quality Management	14
6.2.6 Rationalisation of Local Labelling Requirements	14
6.2.7 Continuous education and improvements	15
7. Conclusion	15
Appendix 1 - References	16
Appendix 2 - UDI Regulatory Landscape	19



Executive Summary

Unique Device Identification (UDI) can strengthen device identification and traceability and support recalls, vigilance and post-market surveillance. However, experience across jurisdictions shows that the effectiveness of UDI depends not only on assigning identifiers or establishing a database, but on how the overall system is designed, implemented and used across the regulatory and healthcare ecosystem.

This paper draws on the evolving global UDI landscape and APACMed member implementation experience to highlight practical considerations for authorities introducing or refining UDI systems. It emphasises the importance of defining clear policy objectives, assessing ecosystem readiness and adopting proportionate implementation approaches that support public-health objectives while avoiding unnecessary complexity and duplication.

APACMed considers the following elements important to an effective UDI system:

- 01

Align with global standards
to support harmonisation and interoperability across jurisdictions.
- 02

Establish a clear and proportionate regulatory scope and strategy,
including appropriate phasing, exemptions and transition arrangements.
- 03

Engage stakeholders and assess ecosystem readiness
so that requirements can be implemented and UDI data can be effectively captured and used.
- 04

Establish robust data governance and quality management
to maintain accurate, reliable and usable UDI data throughout the device lifecycle.
- 05

Rationalise local labelling requirements,
where appropriate, to avoid unnecessary duplication with information available through UDI systems.
- 06

Support continuous education and improvement
through ongoing guidance, stakeholder engagement and monitoring.
- 07

Build scalable and interoperable UDI infrastructure
capable of supporting current requirements and future system needs.

Before implementation, authorities may also wish to assess whether the necessary policy objectives, digital infrastructure, stakeholder capabilities, resources and transition arrangements are in place. The paper therefore combines a **pre-implementation readiness checklist** with practical considerations for the design and ongoing operation of effective UDI systems.

1.Glossary

Application programming interface (API)

API is a set of standard software interrupts, calls, functions, and data formats that can be used by an application program to access network services, devices, or operating systems (ISO 10303-1:2021). [IMDRF Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity]

Machine to Machine

Automated data exchange between computer systems without human intervention. [TGA UDI acronyms and glossary]

UDI Database (UDID)

The UDID contains identifying information and other elements associated with the specific medical device. [IMDRF Unique Device Identification (UDI) of Medical Devices]

Device Identifier (UDI-DI)

The UDI-DI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDID. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-LIC (Labeller Identification Code), ISBT 128-PPIC (Processor Product Identification Code). [IMDRF Unique Device Identification (UDI) of Medical Devices]

Unique Device Identification

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI and UDI-PI. Note: The word "Unique" does not imply serialization of individual production units. [IMDRF Unique Device Identification (UDI) of Medical Devices]

2. Introduction

Unique Device Identification (UDI) systems are being considered or implemented by an increasing number of authorities to support the identification and traceability of medical devices, including recalls and post-market surveillance. Experience across jurisdictions shows that approaches vary significantly, reflecting different regulatory priorities, levels of system maturity and national contexts.

Some authorities are in the process of designing or introducing UDI frameworks, while others are refining systems already in place. In both cases, effective implementation depends on more than establishing UDI requirements or a database. Appropriate infrastructure, system integration and clearly defined use cases are needed to ensure that UDI data can be captured, maintained and used effectively. While the primary purpose of UDI is to enable unambiguous device identification and traceability, implementation should be considered within the broader regulatory and healthcare ecosystem, taking into account existing mechanisms and intended use cases.

This paper is intended primarily for regulatory authorities and policymakers considering the introduction, implementation or refinement of UDI systems. It covers general medical devices (GMDs) and in vitro diagnostic medical devices (IVDs) and draws on publicly available requirements across selected jurisdictions, supplemented by APACMed member implementation experience. The regulatory landscape presented in this paper is illustrative rather than exhaustive and reflects information available as of September 2026.

Purpose of this paper

APACMed aims to support the practical and proportionate design, implementation and refinement of UDI systems. Drawing on industry experience and existing regulatory approaches, the paper outlines key considerations to support alignment with international principles, minimise unnecessary country-specific requirements and enable implementation approaches suited to different regulatory contexts. Its objective is to support effective identification, traceability and post-market activities while avoiding requirements that add operational complexity without a clear contribution to defined public-health objectives.

3. Current UDI Landscape

Existing UDI implementations provide practical experience for regulators developing new systems or refining those already in place. Although implementation approaches differ across jurisdictions, common patterns can be observed in rollout strategies, timelines, and regulatory scope. The figures below provide an overview of the current global UDI landscape and implementation timelines across selected jurisdictions. Detailed country-specific information is available in the landscape tables in Appendix 2.

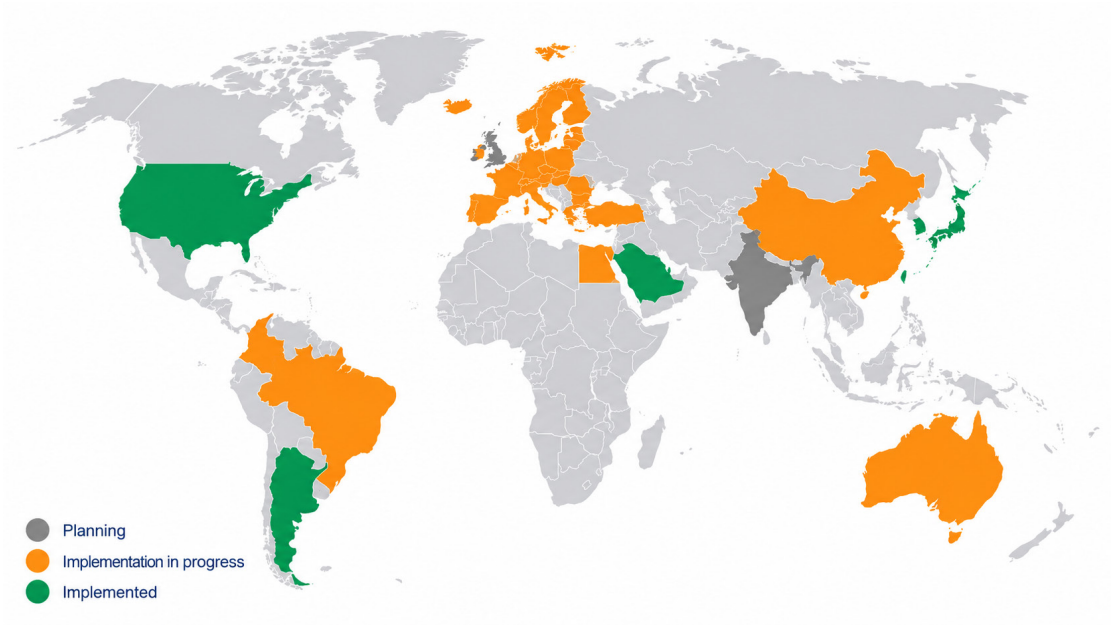


Figure 1. Global Status of UDI Implementation

Beyond implementation status, the pace of implementation also differs across jurisdictions. Figure 2 illustrates the phased nature of UDI database implementation, showing that regulators introduce requirements progressively over several years.

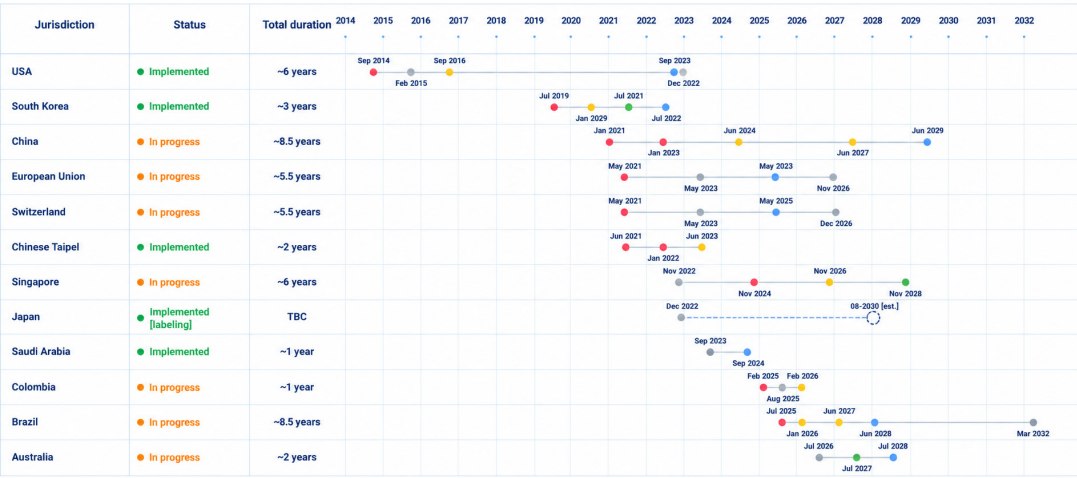


Figure 2. Phased UDI Labelling Implementation Timelines Across Selected Jurisdictions

The landscape shows that UDI is rarely implemented as a single-step requirement. Jurisdictions commonly phase requirements by device risk and/or system element, and the timing of labelling, direct marking and database registration may differ. Building on these observations, the following sections outline the principles that support effective UDI implementation, common pitfalls to avoid, and practical considerations for authorities designing or refining UDI systems.

4. Principles for Effective UDI Implementation

Drawing on the comparative landscape and APACMed member implementation experience across jurisdictions, this paper highlights a number of common principles that can support practical, proportionate, and effective UDI implementation.



Global Alignment

Aligned with internationally recognised principles, terminology, and core UDI concepts (e.g. IMDRF)

Consistent definitions and treatment of core UDI data

Clear distinction between mandatory and optional data elements



Practical Implementation

Least-burdensome and risk-based implementation

Practical, user-friendly, and interoperable database design

Appropriate handling of corrections, updates, and UDI-DI triggers



Fit-for-Purpose Implementation

Implementation designed to support practical post-market use and traceability

Fit-for-purpose implementation reflecting national needs, infrastructure, and healthcare ecosystem readiness

Sufficient transition periods and stakeholder engagement

5. Common Pitfalls to Avoid

Experience across existing UDI systems highlights several common pitfalls that can increase implementation burden and reduce the effectiveness of UDI in practice. The following considerations may help authorities avoid common implementation challenges:

Data & Standards		
Over-customization of data fields beyond globally harmonised standards, leading to increased system complexity and reduced interoperability	Inadequate data validation and correction mechanisms	
IT Infrastructure & System Design		
Lack of Application Programming Interface (API) capabilities and interoperability between enterprise/ company databases and national databases	Lack of bulk upload capabilities and efficient submission / maintenance tools, including versioning controls	Insufficient infrastructure and ecosystem readiness to support effective UDI use in practice
Implementation & Operations		
Heavy operational burden associated with ongoing UDI data management and maintenance	Insufficient consideration of SME capabilities and resource constraints	
Adoption & Use		
Lack of clarity on intended use of and practical value of UDI data	Lack of stakeholder education and awareness across the healthcare ecosystem	

6. Considerations for Authorities Designing or Revising UDI Systems

Designing or refining a UDI system requires more than establishing data requirements or a database. Successful implementation depends on clear policy objectives, appropriate ecosystem readiness, and practical design choices that support effective use while minimising unnecessary burden. The following sections outline key considerations for authorities before and during UDI implementation.

6.1. Pre-Implementation Readiness: Checklist for Authorities

Before deciding to implement UDI, authorities may find it useful to consider the following aspects of system and ecosystem readiness.

Clear policy objective and use cases defined	e.g. recalls, PMS signal detection, supply chain traceability
Clear understanding of international guidance and implementation status in other jurisdictions	e.g.: IMDRF UDI guidance, other jurisdictions' implementation process and methods
Availability and interoperability of digital infrastructure across stakeholders	e.g. ability of systems to exchange and use UDI data across stakeholders (manufacturers, distributors)
Healthcare institutions' capability to capture and integrate UDI	e.g. availability of barcode scanning, integration into clinical workflows, staff training, electronic health records, inventory management, procurement and billing systems
Defined roles and responsibilities for data capture and use	e.g. who captures UDI at each stage, manufacturer, distributor, healthcare provider
Clarity on how UDI data will be used in practice	e.g. for recalls, vigilance, PMS signal detection, beyond database population
Defined approach for migration and treatment of existing device records, including legacy identifiers and alignment with existing registration databases	e.g. whether existing device records, identifiers and registration databases will need to be mapped, integrated or transitioned as part of a future UDI system.



6.2. Considerations for Effective UDI Systems

The following section summarises the key considerations for designing and implementing an effective UDI system. These elements are interconnected and should be considered together to support a proportionate, sustainable and effective approach to UDI implementation.

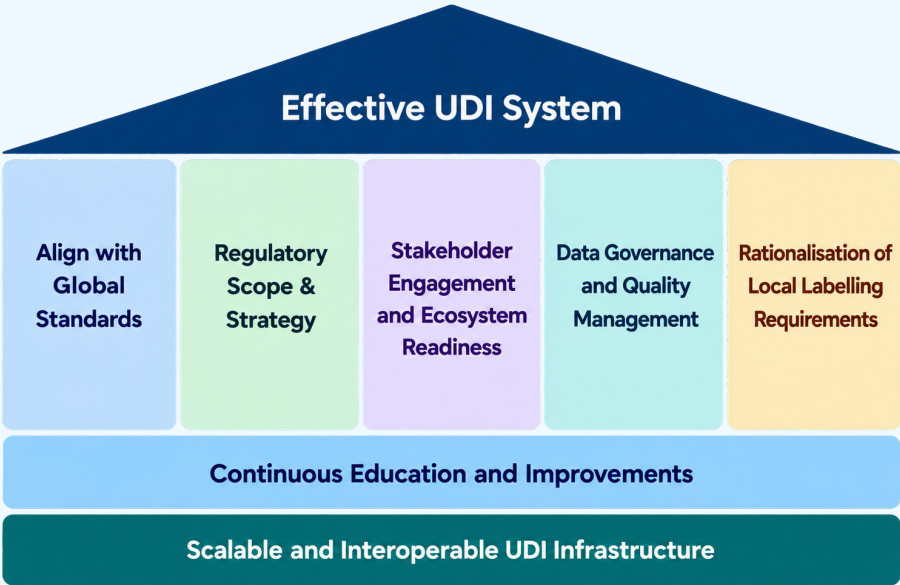


Figure 3. Key Considerations for an Effective UDI System

6.2.1. Align with Global Standards

The IMDRF UDI framework provides an internationally recognised foundation for the design and implementation of UDI systems, covering core principles for UDI assignment, carriers, database requirements, data elements, implementation and use within healthcare systems. Together, the IMDRF guidance documents provide a common reference point that can help authorities avoid unnecessary divergence in terminology, data requirements and system design. Where national adaptations are needed, these can be introduced in a targeted manner while preserving interoperability and consistency with established international approaches.

IMDRF document	Relevance
N7FINAL:2013 – Guidance for UDI of Medical Devices	Core principles for UDI assignment, carrier, UDID, data elements and specific device types
N48FINAL:2019 – UDI System Application Guide	Practical application of the IMDRF UDI framework
N53FINAL:2019 – Use of UDI Data Elements across IMDRF Jurisdictions	Comparison of UDI data elements and differences across jurisdictions
N54FINAL:2019 – System Requirements Related to Use of UDI in Healthcare	Use and capture of UDI within healthcare systems and selected use cases

6.2.2. Regulatory scope & strategy

Recommended Approach	Rationale
Consider proportionate UDI requirements for low-risk Class A/Class I devices, including exemptions or recognition of existing identifiers where appropriate	For some low-risk devices, the incremental traceability benefit of additional UDI requirements may be limited relative to implementation burden. Authorities may consider risk- and use-based exemptions or recognise existing identifiers where these can meet the intended identification and traceability objectives.
Define clear device categories that are excluded or exempt from the UDI framework	Clear criteria for exclusions and exemptions provide regulatory certainty and enable consistent implementation. Where appropriate, exemptions should align with internationally recognised UDI frameworks to support global harmonisation.
Define clear exceptions from specific UDI requirements for device types and supply scenarios	Certain UDI requirements may not be practical for all device types or supply models (i.e. single-use devices, capital equipment, SaMD, devices principally sold at retail, systems and procedure packs, surgical kits, refurbished devices). Exceptions should specify which requirements do not apply or may apply differently (e.g. UDI labelling, direct marking, UDI-DI assignment or database submission), considering device characteristics, lifecycle and established international practices.

Consider practical UDI assignment approaches, such as Master UDI-DI concepts, for highly individualised devices where appropriate E.g. contact lenses, spectacle lenses	Requiring a separate UDI-DI for every minor product variant can generate disproportionate numbers of identifiers and database entries. Grouping similar variants based on defined design parameters can reduce complexity while maintaining appropriate identification and traceability.
Apply direct-marking requirements to reusable devices reprocessed between patients, with clearly defined exceptions. Avoid requiring separate direct marking of individual components unless they are independently placed on the market or require separate identification for safe use or traceability	Exceptions to direct marking should be clearly defined, including where marking is technically infeasible or could adversely affect device safety, performance, functionality or intended use.
Adopt a phased implementation approach based on device risk classification and specific UDI requirements E.g. labelling, database submission, direct marking	Phased implementation provides a pragmatic and manageable approach, helping avoid system overload, minimise implementation risks and support smooth operation of the UDI system.
Define roles and responsibilities for UDI data capture, maintenance and use across relevant stakeholders	Clear responsibilities for UDI data capture, maintenance, update and use help ensure data remains accurate, complete and up to date throughout the device lifecycle and supports effective use across the healthcare system. • Manufacturers bear the foundational responsibilities for UDI creation, application, and master data management. • Distributors and importers act as the vital link verifying that UDI systems remain intact during logistics and trade when necessary. • Hospitals, clinics, and health institutions drive the clinical capture and use of UDI to ensure patient safety and optimize operational efficiency when necessary.
Establish clear transitional arrangements for existing devices manufactured and labelled before the applicable UDI compliance date	Establishing transitional arrangements for existing devices support a phased and proportionate implementation of UDI, minimise unnecessary supply-chain disruption and regulatory burden, and facilitate alignment with established international UDI practices. Retrieving or relabelling devices already held by hospitals, distributors, or patients could also disrupt established supply chains and continuity of patient care. Applying direct-marking requirements retrospectively to devices manufactured before the relevant compliance date requires physical modification of finished devices which not always be technically feasible and could affect device integrity, validated manufacturing processes, regulatory approvals, or patient safety.

¹ listed examples are illustrative, not proposed blanket exemptions

² For an example of this approach in practice, refer to the EU Master UDI-DI framework for contact lenses and spectacles: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202302197 & https://health.ec.europa.eu/document/download/f026ed58-060d-49b1-b660-914838670a20_en?filename=mdcg_2025-8_en.pdf

6.2.3. Stakeholder Engagement and Ecosystem Readiness

Successful UDI implementation requires not only assigning and registering identifiers, but also enabling their capture and use across the healthcare ecosystem.



6.2.4. Scalable and Interoperable UDI Infrastructure

UDI systems should be supported by scalable, interoperable and secure digital infrastructure that can accommodate increasing data volumes, enable efficient data exchange and adapt to future needs.

Scalability by Design

- Accommodate increasing data volumes as UDI expands across device classes and economic operators.
- Support high-volume data handling, including bulk uploads and machine-to-machine (M2M) data exchange.
- Allow specific system components to scale independently (e.g. data submission vs. reporting).
- Consider future system needs from the outset to avoid significant redesign as the UDI framework evolves.
- Support appropriate operational resilience, including backup, recovery, service continuity and incident-management arrangements.

Interoperability and Connectivity

Support interoperability and/or connectivity with relevant national systems (e.g. customs, import/export controls, vigilance databases and healthcare systems), where applicable, to enable data exchange and avoid unnecessary duplication.

Recommended IT Architecture

- Align the data model with IMDRF UDI data elements and terminology.
- Define clear data access levels, distinguishing public UDI information, restricted submitter information, and authority-only data.
- Support flexible submission channels, including manual entry for low-volume users and structured bulk/API submission for high-volume users.
- Enable API-based machine-to-machine (M2M) exchange to support automated system-to-system data submission and integration.
- Support bulk data submission (e.g. XML/JSON) alongside a web-based interface for manual entry.
- Provide structured mechanisms for data correction and updates after submission, including appropriate grace periods.
- Ensure secure and controlled connectivity, including encrypted data transmission (e.g., HTTPS/TLS), authentication (e.g., API keys, OAuth), and role-based access controls.
- Maintain a clear record lifecycle and history, including relevant record statuses (e.g. draft, submitted, validated, published, corrected, superseded, withdrawn and archived), visibility of current and historical versions, effective dates and reasons for changes.
- Apply data validation and integrity controls, including automated validation rules, standardised vocabularies and structured data formats.
- Ensure auditability and reliable data exchange through audit trails, version control, structured acknowledgements, actionable error messages and asynchronous processing where needed.

6.2.5. Data Governance and Quality Management

Robust data governance and established data management processes are critical to ensure the reliability, accuracy and usability of UDI data throughout the product lifecycle. Key components include:

- Clearly defined data ownership and responsibilities between manufacturers and authorities
- Appropriate controls for data access and management
- Comprehensive audit trails and version control
- Automated data validation rules at data entry and update
- Use of standardised nomenclature (e.g. GMDN) to support data consistency
- Established processes for data capture, maintenance, update and correction throughout the product lifecycle

6.2.6. Rationalisation of Local Labelling Requirements

UDI implementation provides an opportunity to review local labelling requirements and reduce duplication with information already captured and accessible electronically.

- Avoid duplicating information on physical labels where it is already captured and accessible through the UDI system, supporting a single source of truth.
- Where local information (e.g. Authorised Representative or importer details) is maintained within the UDI database, consider removing it from mandatory physical labelling requirements or allowing it to be provided electronically.
- Support the use of electronic Instructions for Use (e-IFU), e-Labeling or database access, where appropriate.
- Apply a risk-based approach so that critical point-of-use information remains on the physical label, while non-critical or frequently changing information can be maintained digitally.
- Enable more efficient updates without unnecessary physical relabelling.
- Promote greater alignment across APAC markets to reduce unnecessary burden and the risk of inconsistencies created by divergent local labelling requirements.

6.2.7. Continuous education and improvements

Once implemented, UDI systems should be supported by ongoing guidance, stakeholder engagement and monitoring to address implementation challenges and support continuous improvement.

- Provide ongoing training and accessible guidance (e.g. FAQs).
- Establish a dedicated UDI support function to address implementation and technical queries.
- Maintain ongoing stakeholder engagement to identify implementation challenges and areas requiring further support.
- Define appropriate KPIs to measure the effectiveness of UDI implementation and integration and assess progress against its intended objectives.
- Use implementation experience, stakeholder feedback and performance indicators to inform future system improvements.

7. Conclusion

UDI can strengthen device identification and traceability and support more effective recalls, vigilance and post-market surveillance. However, experience across jurisdictions shows that these benefits depend not only on assigning identifiers or establishing a database, but on how the overall system is designed, implemented and used across the regulatory and healthcare ecosystem.

APACMed therefore supports UDI approaches that are aligned with internationally recognised principles, proportionate to risk and intended use cases, supported by appropriate infrastructure and stakeholder readiness, and introduced through realistic transition arrangements. Clear governance, practical data requirements, interoperable systems and ongoing stakeholder engagement are also important to ensure that UDI data remains accurate, usable and able to support its intended regulatory and public-health objectives.

As authorities across APAC continue to introduce or refine UDI frameworks, applying these considerations can help support effective implementation while preserving sufficient flexibility for national needs and avoiding unnecessary complexity or duplication.

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Appendix 2 – UDI Regulatory Landscape

This landscape reflects information available as of September 2026 and is divided into APAC and other markets for ease of reference. Regulatory requirements are subject to change; please refer to official sources for the latest information. Where no separate IVD timeline is shown, IVDs generally follow the applicable device-class implementation timeline unless otherwise specified.

APAC Market	Status	Device Risk Classification	Device package labels		Direct marking of devices		UDI Database	
			Required?	Compliance Date	Required?	Compliance Date	Name	Submission date
Australia ³	In Progress	Class III	Yes	1 July 2026	Yes	1 January 2028	AusUDID	1 July 2026
		Class IIb		1 July 2026		1 July 2029		1 July 2026
		Class IIa		1 July 2027		1 July 2029		1 July 2027
		Class Is, Class 4 IVD, Class 3 IVD		1 July 2028		1 July 2029		1 July 2028
		Class 1 IVD (instruments/software), Class 2 IVD		1 July 2029		1 July 2030		1 July 2029
China	In Progress	Class III (69 devices)	Yes	1 Jan 2021	Required for applicable reusable devices	As applicable	NMPA UDID	1 Jan 2021
		Class III (others):		1 June 2022				1 June 2022
		Class II (103 devices)		1 June 2024				1 June 2024
		Class II (rest)		1 June 2027				1 June 2027
		Class I IVDs		1 Jun 2027				1 Jun 2027
		Class I		1 June 2029				1 June 2029
Chinese Taipei	Implemented	Class III (implantable)	Yes	1 June 2021	As applicable	NA	TUDID	1 June 2021
		Class III (non-implantable)		1 June 2022				1 June 2022
		Class II		1 June 2023				1 June 2023
India	Planning	TBC	TBC	TBC	TBC ⁴	TBC	TBC	TBC
Japan	Implemented (labelling)	Class III	Yes	1 December 2022	Conditionally Required	TBC	Under development	Estimated 2028
		Class II and I		1 December 2022				Estimated 2028
Malaysia	Planning	Class D	Yes	2027	TBC	TBC	Medc@st 3.0	2027
		Classes B, C		2028				2028
		Class A		TBC				TBC
Singapore	In Progress	All Coronary stents, orthopaedic joint replacement implants and Intraocular lens	Yes	1 Nov 2022	Voluntary	Voluntary	SMDR	1 Nov 2022
		All Class D GMDs and IVDs		1 Nov 2024				1 Nov 2024
		All Class C GMDs and IVDs		1 Nov 2026				1 Nov 2026
		All Class B GMDs and IVDs		1 Nov 2028				1 Nov 2028
		All Class A GMDs and IVDs		Voluntary				Voluntary
South Korea	Implemented	Class IV	Yes	1 July 2019	To be Conditionally Required ⁵	TBC	IMDIS	1 July 2019
		Class III		1 July 2020				1 July 2020
		Class II		1 July 2021				1 July 2021
		Class I		1 July 2022				1 July 2022

³ Transitional arrangements may apply to devices relying on eligible EU MDD/IVDD certification. Refer to TGA guidance for the applicable UDI compliance dates. Direct marking requirements apply based on the relevant device class and transitional arrangements.

⁴ For markets with “TBC”, an official intention to implement UDI has been published, but implementation details are yet to be released.

⁵ Devices must be included in a list published by MFDS (MFDS hasn’t published the list yet)

Non-APAC Market	Status	Device Risk Classification	Device package labels		Direct marking of devices		UDI Database	
			Required?	Compliance Date	Required?	Compliance Date	Name	Submission date
Argentina ⁶	Implemented (limited scope)	Certain Implantable Medical Devices	Yes	2014	No	N/A	SNT-PM	2014
Brazil	In Progress	Class IV	Yes	10 Jul 2025	Conditionally Required	10 Jul 2027	SIUD	1 Sep 2029
		Class III		10 Jan 2026		10 Jan 2028		1 Mar 2030
		Class II		10 Jan 2027		10 Jan 2029		1 Mar 2031
		Class I		10 Jan 2028		10 Jan 2030		1 Mar 2032
Colombia	In Progress	Class III, Category III IVD	No	NA	No	NA	INVIMA semantic standard platform ⁶	Feb 2025
		Class IIb, Category II IVD						Aug 2025
		Class IIa, Class I, Category I IVD						Feb 2026
Egypt ⁷	In Progress	All Classes	TBC	TBC	Conditionally Required	TBC	Egyptian UDI Database	TBC
Europe	In Progress	Class III and Implantable	Yes	26 May 2021	Conditionally Required	26 May 2023	EUDAMED	New devices: 28 May 2026 Devices already placed on the market: 28th November 2026
		Class IIa, IIb and IVD Class D		26 May 2023		26 May 2025		
		Class I and IVD Class B and C		26 May 2025		26 May 2027		
		IVD Class A		26 May 2027		26 May 2029		
Saudi Arabia	Implemented	Class D (High Risk)	Yes	1 Sep 2023	Conditionally Required	1 Sep 2024	Saudi-DI	1 Sep 2023
		Class B and C (Medium Risk)		1 Sep 2023		1 Sep 2024		1 Sep 2023
		Class A (Low risk)		1 Sep 2024		1 Sep 2025		1 Sep 2024
Switzerland	In Progress	Class III and Implantable	Yes	26 May 2021	Conditionally Required	26 May 2023	SWISSDAMED	1 Jul 2026 (transition period until 31 Dec 2026)
		Class IIa and IIb, IVD Class D		26 May 2023		26 May 2025		
		Class I, IVD Class B/C		26 May 2025		26 May 2027		
		IVD Class A		26 May 2027		26 May 2029		
Turkey	In Progress	Class III & implantable	Yes	26 May 2021	Conditionally Required	26 May 2023	ÜTS	TBC
		Class IIa & IIb + IVD Class D		26 May 2023		26 May 2025		
		Class I + IVD Classes B/C		26 May 2025		26 May 2027		
		IVD Class A		26 May 2027		26 May 2029		
UK	Planning	TBC	TBC	TBC	TBC	TBC	TBC	TBC
USA	Implemented	Implantable, life-supporting and life-sustaining devices, regardless of device class	Yes	24 Sep 2015	Conditionally Required	24 Sep 2015	GUDID	24 Sep 2015
		Class III & and devices licenced under the Public Health service Act		24 Sep 2014		24 Sep 2016		24 Sep 2014
		Class II		24 Sep 2016		24 Sep 2018		24 Sept 2016
		Class I		24 Sep 2022		24 Sep 2022		8 Dec 2022

⁶ UDI requirements apply to a limited scope of implantable medical devices. Direct marking is not required.

⁷ The 2026 EDA UDI guideline covers medical devices and IVDs; enforcement timelines for UDI labelling and direct marking are yet to be announced.

About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. For more information, visit www.apacmed.org