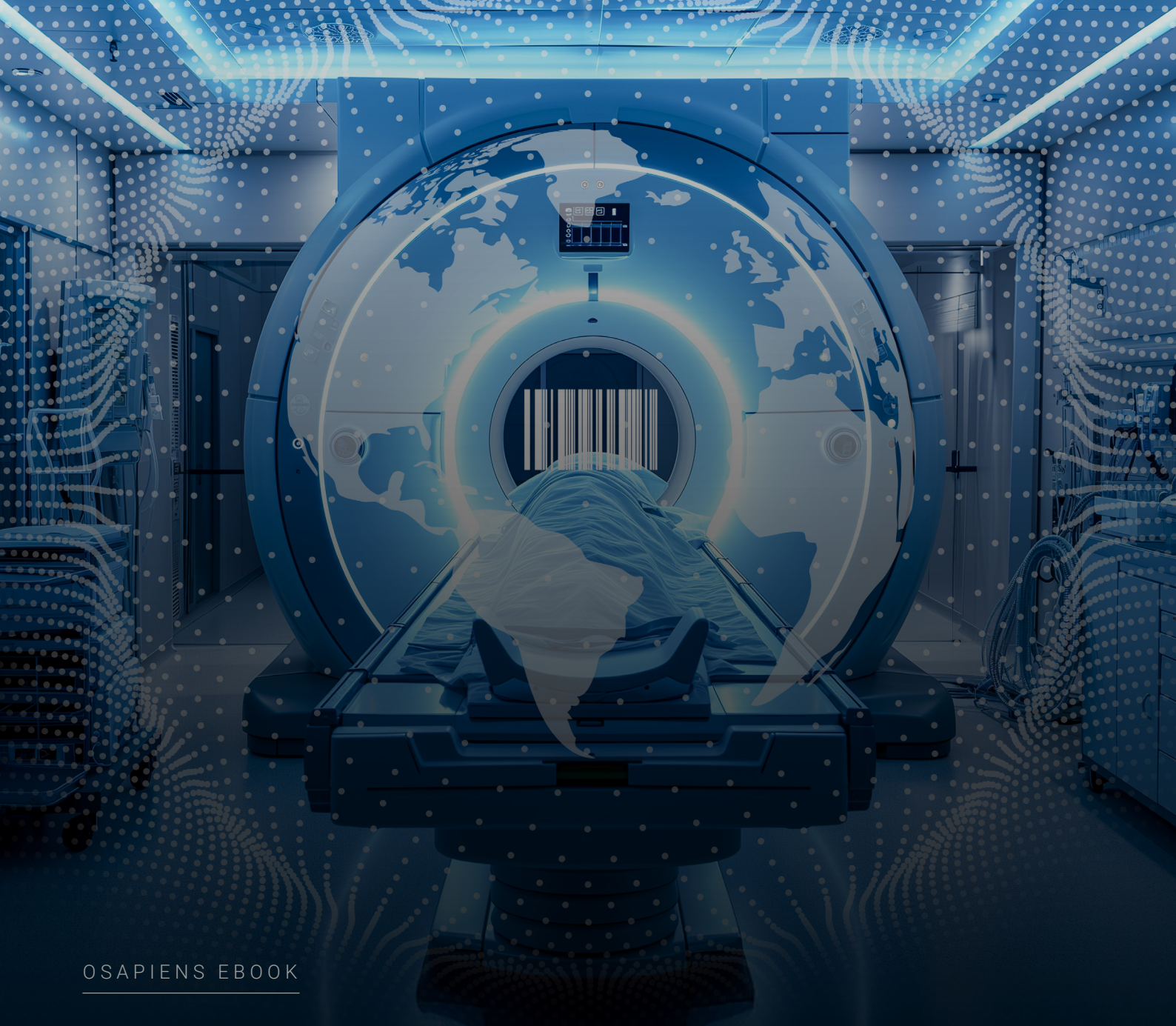


OSAPIENS EBOOK

MASTERING GLOBAL UDI COMPLIANCE: A PRACTICAL GUIDE FOR MEDTECH COMPANIES

Handbook of Global Regulations
in Medical Devices

osapiens®

Foreword

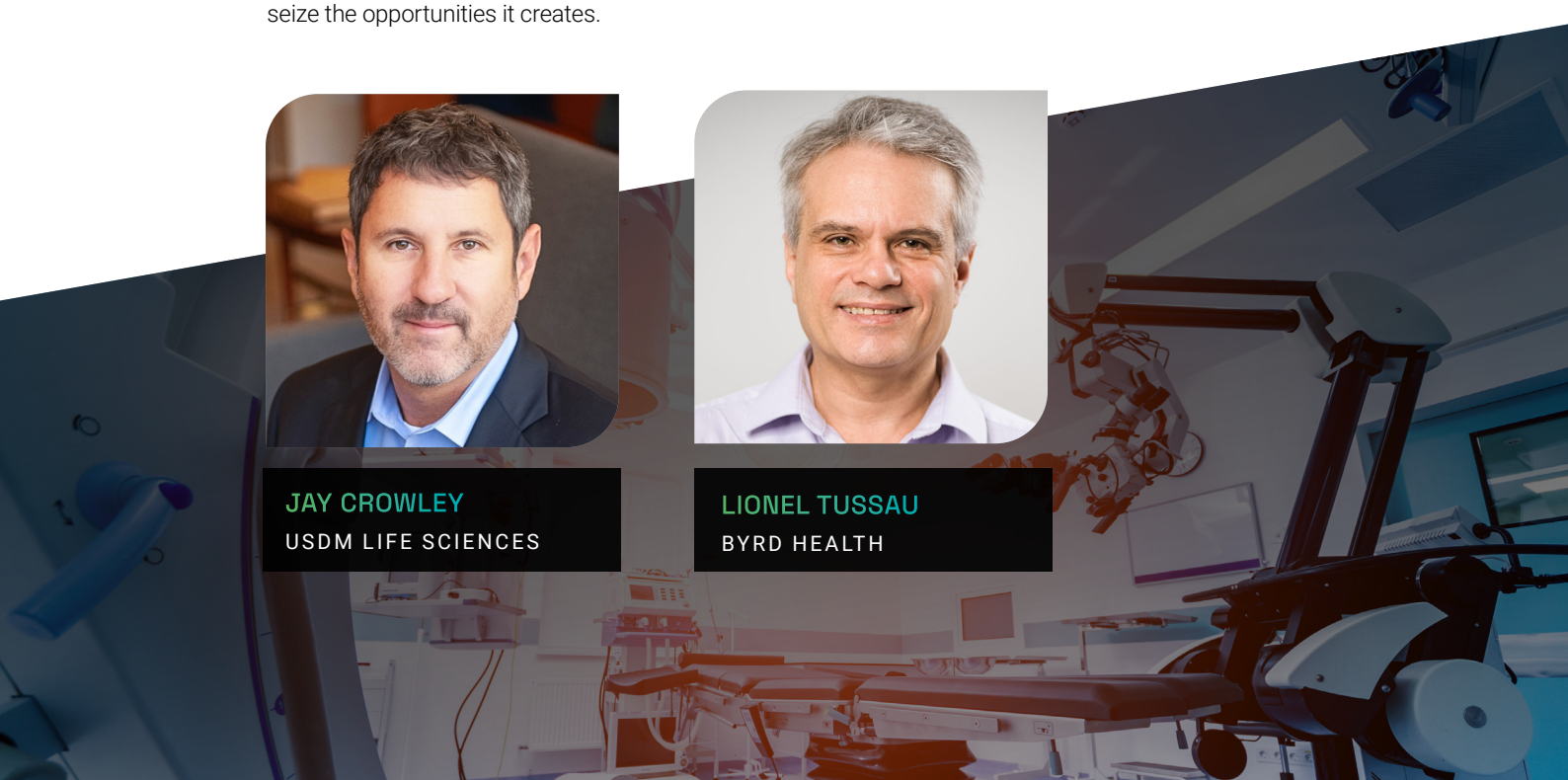
Dear MedTech Professional,

From our combined experience across the United States, Europe, and beyond, we know how challenging it is for medical device manufacturers to navigate the patchwork of UDI regulations globally. Each market comes with its own obligations. Compliance is not a simple checklist – it is the foundation for patient safety, product trust, and market access.

In our work with MedTech companies of all sizes, we have seen recurring challenges. Manufacturers often underestimate the effort required to translate Enterprise Resource Planning (ERP) attributes, as well as those from Product Lifecycle Management (PLM) systems into healthcare-specific standards. Data is all over the place – some only exist in the label itself, or sometimes in a Technical Document. Companies also tend to overlook the complexity to update accurate product content against evolving regulations in validated environments. Fragmented processes and missed deadlines create costly rework and delayed market entries.

Conversely, companies that invest in structured workflows, centralized managed product content, and proactive validation turn these obligations into operational advantages. This handbook is a practical reference for global healthcare. It guides MedTech companies through readiness assessment, process alignment, and data governance, delivering actionable insights from real-world experience. By mastering UDI globally, healthcare companies can optimize regulatory compliance. To support this, the handbook provides comprehensive UDI requirements globally and detailed country profiles, offering a broad view of regulatory expectations across key markets worldwide.

We hope this book helps you to navigate the complex landscape of global UDI compliance – and to seize the opportunities it creates.



JAY CROWLEY
USDM LIFE SCIENCES

LIONEL TUSSAU
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Executive Summary

Legal manufacturers (labelers in the US) of products defined legally as medical devices, including in-vitro diagnostics, face a regulatory landscape that is more fragmented in global markets and demanding than ever before. Since the US Food and Drug Administration (FDA) introduced the first binding Unique Device Identification (UDI) System regulatory requirements in 2013, other major markets including Australia, China, the European Union and Switzerland– have established their own UDI requirements. Today, UDI Databases, such as the FDA's GUDID in the US and EUDAMED in the EU set the standard for device identification, requiring manufacturers to submit detailed UDI device information that help to support traceability. Though the general UDI System requirements are similar, the divergent requirements for classification, data formats, and timelines strains resources at MedTech companies and creates the constant risk of delayed approvals or market entry barriers.

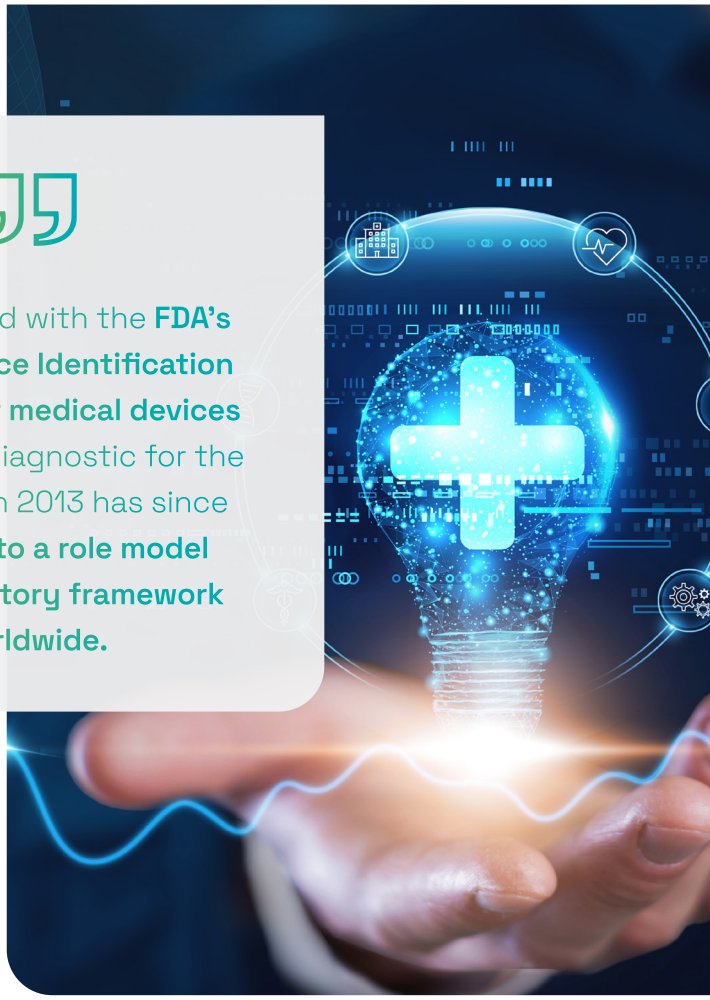
Non-compliance is no longer an administrative issue – it is a strategic risk. Companies that treat compliance as a last-minute, market-by-market exercise face duplication of effort, rising costs, delays in product launches, even fines and exclusion from key markets. For manufacturers, the challenge goes beyond preparing the initial UDI data set: they must create and submit compliant product content to national databases and maintain this information – and regulatory compliance – over time.

This handbook provides a practical roadmap for medical device manufacturers mastering global UDI compliance. It guides companies to implementing readiness strategies, aligning internal processes, and ensuring data quality and reuse across global markets. By standardizing product content and adopting structured workflows, companies can streamline submissions across multiple jurisdictions.

osapiens for Medical Devices (BYRD Health) equips MedTech manufacturers with powerful digital tools to manage UDI requirements efficiently across global markets. Its platform centralizes product master data, helps to transform attributes from PLM and/or ERP Systems into validated, submission-ready content for regulatory authorities. Automated workflows flag data gaps before publication, while real-time dashboards provide full transparency into regulatory readiness and submission progress. Beyond technology, osapiens for Medical Devices (BYRD Health) provides early access to regulatory changes and best practices through exclusive user groups and expert advisory services – helping manufacturers stay ahead in a rapidly evolving compliance landscape.

01. Introduction

MedTech companies keep expanding into new more markets than ever before, driven by global growth opportunities, strategic acquisitions, and increased demand for medical devices worldwide in regions such as the US, Europe, and Asia-Pacific. Yet with every step across borders, companies face an increasingly fragmented set of regulatory demands. What started with the US FDA's Unique Device Identification (UDI) System rule for medical devices and in vitro diagnostic for the US market in 2013 has since evolved into a role model for regulatory frameworks worldwide. Each jurisdiction enforces its own UDI requirements, submission formats, and databases.



> What started with the **FDA's Unique Device Identification (UDI) rule for medical devices** and in vitro diagnostic for the US market in 2013 has since **evolved into a role model for a regulatory framework worldwide.**

For manufacturers, this regulatory patchwork is a significant challenge: Those who master compliance can access the world's most valuable healthcare markets. Those who struggle or fail to adapt risk costly delays, exclusion, and reputational damage.

As countries and their regulatory requirements mature, many have also added UDI requirements to solve certain local problems. This is what causes much of the complexity.

1.1 Why regulatory compliance is critical for patient safety, product trust and market access

For MedTech companies, regulatory compliance and the binding obligation to UDI is not a bureaucratic formality – it is the backbone of modern medical device regulation. By assigning every device a unique, traceable identifier, regulators and healthcare providers gain the ability to track products across their entire lifecycle. This traceability enables faster, more effective post-market surveillance and a rapid response in the event of defects or safety concerns, reducing risks for patients and ensuring that corrective measures reach the market quickly.

From a business perspective, compliance is part of the gateway for MedTech manufacturers to market access. Regulatory authorities in the United States, the European Union, China, and other key markets may block products that fail to meet requirements, leading to recalls, delays in product launches, or even long-term exclusion from strategic markets. At the same time, hospitals and group purchasing organizations increasingly favor suppliers who can ensure seamless compliance, as this reduces operational risk and streamlines supply chain management.

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1.2 Barriers to global alignment: The diversity of political, economical and healthcare structures

The ambition of a single harmonized approach to UDI has unfortunately run into hard realities. Regulators and healthcare systems differ fundamentally between regions, shaped by political priorities, economic structures, and historical development. What works in the United States – a market-driven system with the FDA as a strong central authority – looks very different in the European Union, where many member states operate under a shared legal framework but retain national oversight in practice. In many markets, governments use regulatory requirements

not only to protect patients but also to strengthen domestic industries and assert sovereignty over data. This often results in the introduction of unique attributes or technical formats. For manufacturers, this means every jurisdiction introduces its own version of UDI – similar in principle, divergent in execution.

Economics amplify these differences. High-income markets demand comprehensive reporting and frequent updates, supported by advanced IT infrastructures. In contrast, some middle-income countries adopt step-by-step approaches, focusing first on core identifiers while delaying full database integration. This uneven pace of adoption forces global MedTech companies to manage a patchwork of regulatory maturity levels.

The healthcare structures themselves add another layer of complexity. In some markets, large group purchasing organizations and hospital networks expect seamless integration with national databases. In others, procurement is fragmented, increasing the pressure for healthcare companies to adapt submissions country by country.

The outcome is a regulatory landscape that reflects not only technical standards but also political and economic realities. True global alignment remains out of reach. For manufacturers, the challenge is not to wait for harmonization, but to design compliance strategies resilient enough to absorb these differences while maintaining efficiency and speed to market.

02.
Understanding UDI: a global perspective

UDI has become a cornerstone of medical device regulation, yet its practical implementation differs widely across regions. Understanding the origins, guiding principles, and structural components of UDI helps to build a robust compliance strategies on a global scale.

2.1. The origins and purpose of the UDI system: improving traceability and post-market surveillance

The Unique Device Identification system started in the United States. In 2013, the FDA introduced a regulation, requiring medical devices to carry a standardized identifier and to be registered in FDA's Global UDI Database (GUDID). It was the first binding regulation of its kind worldwide.

The goal was to improve identification and traceability of medical devices, streamline their post-market surveillance, and allow regulators, manufacturers, and other stakeholders to respond rapidly to safety concerns. Over the past decade, UDI regulatory requirements have expanded globally. While inspired by the FDA framework, each region adapts the concept to local regulatory priorities and technical infrastructures, creating a patchwork of implementation requirements.

2.2. The role of the International Medical Device Regulators Forum (IMDRF): guiding principles

The International Medical Device Regulators Forum (IMDRF) plays a critical role in shaping UDI systems worldwide. Established in 2011, the IMDRF developed the foundational guidelines for UDI, including a common framework for device identification and data submission. Its documents set the baseline for regulators in the United States, the European Union, China, Australia, and many other regions.

What is the UDI-DI?

Unique Device Identifier (UDI) is a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and allows unambiguous identification of specific devices on the market.

UDI-DI (Device Identifier) is the part of the UDI that uniquely identifies a medical device or system, providing key information such as manufacturer, model, serial number and manufacturing or expiration date of the product. It remains unchanged throughout the product's lifecycle. Manufacturers must register UDI-DI in EUDAMED for compliance with European regulatory requirements.

UDI-DI is a unique code + characteristics

Specific to model/variation/version

UDI-**DI**
Device Identifier used as the „access key" to information stored in the UDI database

Source: Infographics, European Commission (https://webgate.ec.europa.eu/eudamed-help/en/getting-started/infographics.html)

IMDRF does not enforce regulations. Instead, it promotes consistency and interoperability by providing the guiding principles. Regulators interpret these guidelines and implement them in their own legal frameworks. For medical device manufacturers, understanding IMDRF's work helps anticipate future requirements, reuse data across regions, and align global compliance strategies more effectively.

2.3. Global harmonization versus regional interpretation

While IMDRF principles aim to promote global harmonization, individual regulators interpret and implement the rule-based requirements set by the respective authorities for UDI differently. Required data attributes, accepted UDI issuing agencies, technical formats, and upload mechanisms vary widely. Some jurisdictions allow bulk uploads via automated systems, others lack this sophistication and therefore require manual entry. This divergence forces manufacturers to reconcile multiple regional standards, each with operational and compliance implications.

2.4. Core components of a UDI system

Despite regional differences, all UDI frameworks share essential building blocks. They include:

- **UDI-DI (Device Identifier):** identifies a device model for regulatory tracking and post-market surveillance.
- **UDI-PI (Production Identifier):** captures production-specific information such as serial number, manufacturing and expiration date.
- **Labeling:** specifies how the UDI must appear on a device label and its packaging.
- **Direct Marking:** requires reusable devices to carry a permanent, durable UDI for traceability throughout the product lifecycle.
- **Registration:** submission of device and identifier data to a regulatory database such as GUDID or EUDAMED, or other national UDI Databases.

Unique Device Identification (UDI) is a globally unique accession code – comprising a fixed Device Identifier (UDI-DI) and a variable Production Identifier (UDI-PI) – that ensures unambiguous identification of a medical device on the market, enabling accurate traceability, improved patient safety, and streamlined regulatory submissions.

03.

Global UDI requirements by country

	 USA	 European Union, Turkey, Norway, Iceland, Northern Ireland, Liechtenstein	 Switzerland
Name of regulation	CFR 21 Part 830	MDR (2017/745) and IVDR (2017/746)	MedDO 812.213
Name of the UDI database	GUDID	EUDAMED	swissdamed
Regulator	FDA	European Commission	Swissmedic
Compliance deadlines for UDI registration	All medical devices must be registered in GUDID beforebeing placed on the US market (except if they are exempt)	Expected to be **May 2026** for devices placed on the market after that date / **November 2026** for devices already on the market – same deadline applies to all risk classes	**July 2026** for devices subject to Post Market Surveillance activities; otherwise December 2026
Number of attributes	57	120	116
UDI Database Specificities	Data can be corrected after the 30 day grace period by using the „unlock" function in the GUDID and submitting the corrected information (this is not allowed if a new UDI is required): see GUDID User Manual 2.1 from December 2024	A device is identified by both its Basic UDI-DI at model leve, and the UDI-DI at the device level - both need to be registered in EUDAMED (see BYRD Health eBook on EUDAMED for further details). The UDI module is linked to the Certificate module where additional Certificate information is entered by Notified bodies at the Basic UDI-DI level. Contact lenses and some eyewear devices are identified by a Master UDI-DI (MUDI) instead of a UDI-DI.The UDI module will be linked to the Vigilance module for some Device information.	–
Machine to machine upload	Yes	Yes	Planned for 2026
Other upload process	Manual UI UDI per UDI	Manual XML upload, Manual UI	Manuap XML upload + manual data enrichment UDI by UDI in the swissdamed UI
Live with BYRD Health	Yes	Yes	Date TBC
Labelling and direct marketing deadlines	Labeling and Direct marking deadlines are in the past	All devices placed on the Union market must already have a UDI labeled – except for IVD Class A, for which the deadline is still to come: 26 May 2027. Reusable devices must already have a Direct Marking – except for Class I devices; for which the deadline is still to come: 26 May 2027	All devices placed on the Swiss market must already have a UDI labeled. Reusable devices must already have a Direct Marking - except for Class I devices; for which the deadline is still to come : 26 May 2027
GDSN with trading partners	Yes – with some Hospitalts/GPOs	Yes – depending on Member State	Yes – hospitals
Post market surveillance	Yes – outside of GUDID: see CFR 21 Part 822	Yes – Vigilance module in EUDAMED, expected to be live and mandatory in September 2026	Yes – outside of swissdamed (see MedDO)
Issuing agencies	GS1, HIBCC, ICCBBA	GS1, HIBCC, ICCBBA, IFA	GS1, HIBCC, ICCBBA, IFA

	 Saudi Arabia	 China	 Australia
Name of regulation	MDS-G34	Regulations on Supervision and Administration of Medical Devices	*Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025*.
Name of the UDI database	Saudi-DI	CUDID	AusUDID
Regulator	Saudi FDA	NMPA	TGA
Compliance deadlines for UDI registration	All medical devices must be registered in Saudi-DI before they are put on the Saudi market	**October 2026** for Class I products. Class III and II must already be registered in the Chinese UDI database	**Class III and Class IIb:** 1st July 2026; **Class Iia:** 1st July 2027; **Class I:** 1st July 2028
Number of attributes	–	–	–
UDI Database Specificities	The data model is similar (but not identical) to the GUDID data model	Some Chinese specific fields are mandatory; descriptions must be provided in Chinese characters	In Australia, a UDI-DI can be updated by different actors due to the „sponsor" concept
Machine to machine upload	No	Yes	Yes
Other upload process	Excel upload	Manual UI	Manual UI
Live with BYRD Health	Yes	Date TBC	in final testing phase
Labelling and direct marketing deadlines	All compliance deadlines are in the past.	All devices placed on the Chinese market must already have a UDI labeled, except for Class I devices; for which the deadline is expected to be October 2026	**LABLING** **Class III and Class IIb:** 1st July 2026; **Class Iia:** 1st July 2027; **Class I:** 1st July 2028 **IVD Class 4 and 3:** 1st July 2028; **Class 2 and 1:** 1st July 2029 **DIRECT MARKING** **Class III:** 1st Jan 2028; **Class IIb:** 1st Jan 2029; **Class Iia and I:** 1st Jan 2029 **IVD Class 4 and 3:** 1st July 2029; **Class 2 and 1:** 1st July 2030 Special dates apply for EU legacy devices placed on the Australian market
GDSN with trading partners	No	No	No
Post market surveillance	Ye – but outside of Saudi-DI	Yes – but outside of CUDID	Yes – but outside of AusUDID
Issuing agencies	GS1, HIBCC, ICCBBA	GS1, ZIIOT, Ali Health, the Mashangfangxin Platform	GS1, HIBCC, ICCBBA

04.

Roadmap for practical implementation of global compliance strategies

> "Centralizing our product master data with **BYRD Health** allowed us to **catch errors before submission.** We've seen a noticeable drop in rejection rates."

Global UDI compliance cannot be addressed with ad hoc, market-by-market solutions. MedTech manufacturers face a fragmented landscape of divergent standards, submission formats, and product content requirements. Without a clear roadmap, companies risk delays, increased costs, and operational inefficiencies.

Implementing compliance at a global scale requires a structured, programmatic approach. Leading manufacturers treat UDI not as a one-off checklist but as a continuous strategic initiative spanning assessment, planning, execution, and ongoing monitoring.

4.1. Assessment, planning, and execution: Developing a global regulatory compliance strategy

Global UDI compliance starts long before the first submission of product content. Medical device manufacturers are well advised to first map requirements across all target markets and identifying gaps in current processes. This assessment must cover UDI obligations, device classification rules, and database submission requirements for each jurisdiction.

On this foundation, compliance teams can develop a structured plan. Based on best practices, regulatory managers are advised to assign responsibilities across departments, project leads to set realistic timelines, and IT leverages tools for data validation, updates, and reporting. Product teams should focus on priority markets, test processes, train staff, and align systems with regulatory expectations.

Collaboration is essential. Quality, IT, and operations teams must work in sync to embed new workflows seamlessly into daily operations, while senior management monitors progress, resolves bottlenecks, and ensures compliance supports broader business goals. Without collaboration, it will be impossible to reach a Single Source of Truth and align with other regulatory and commercial requirements (e.g. labels, IFUs, post-market surveillance activities, recalls…)

4.2. Product registration and approval: Navigating submission requirements

Product registration and approval is a core requirement under global UDI regulations. MedTech manufacturers must first assign a UDI to each device through an accredited issuing agency, applying it to the label and packaging and submit the information with the relevant national database, such as the FDA's GUDID in the US or EUDAMED in the EU.

> **"Readiness does not begin at the point of submission,** it is build upstream. It starts during the preparatory phase, when companies test and validate their product content and workflows. Using sandbox environments gives manufacturers the opportunity to detect inconsistencies early and correct them before go-live."

JAY CROWLEY

Vice President of Medical Device Solutions and Services at USDM Life Sciences.

Automated workflows and machine-to-machine transfers help streamline this process, reducing manual errors, and speeding approvals. By standardizing documentation and establishing repeatable processes, companies can manage multiple markets more efficiently while keeping records up-to-date and audit-ready.

4.3. Alignment of product content: Management with global standards

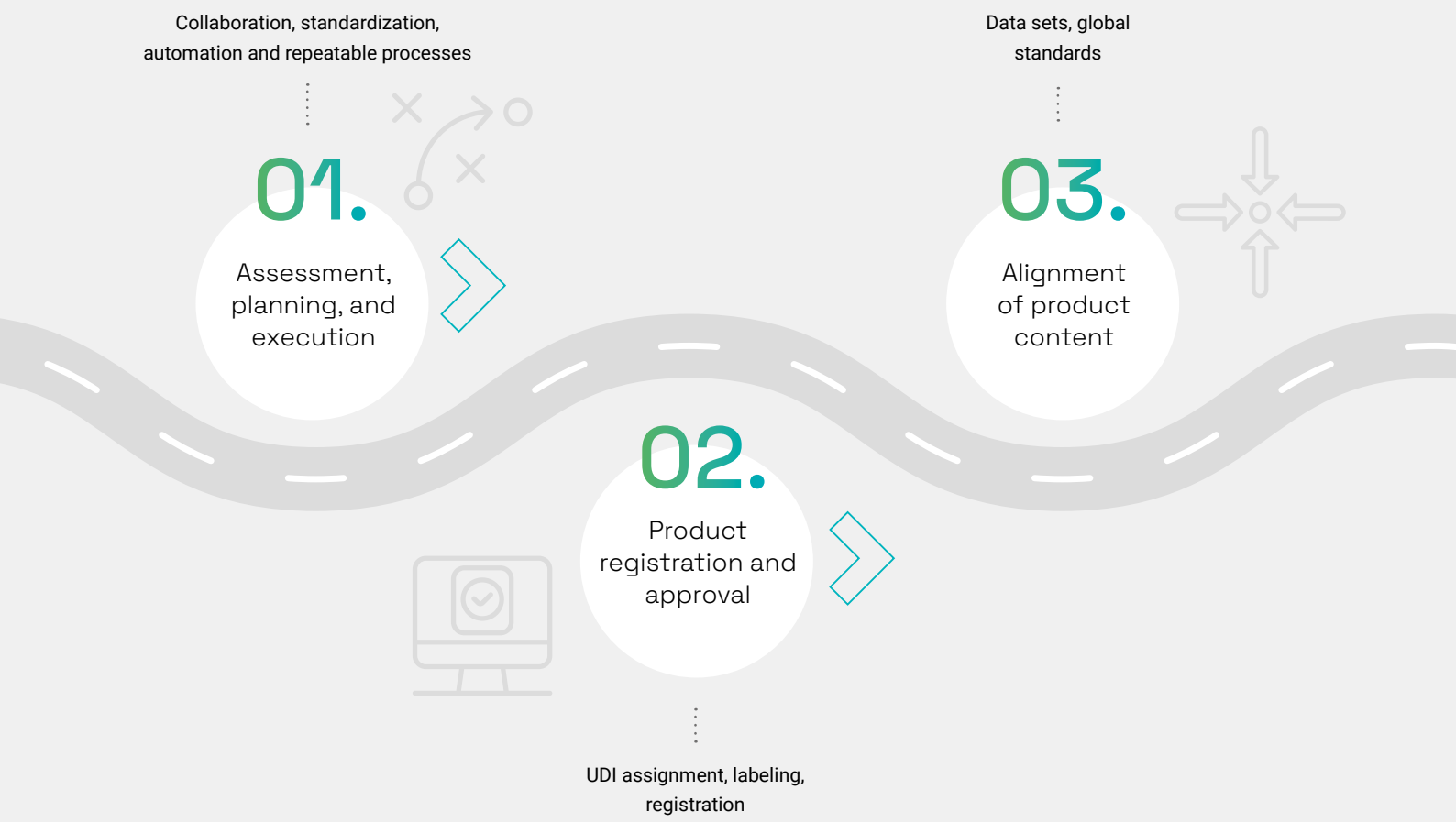
For MedTech manufacturers product content is a cornerstone of global compliance. Each regulator demands accurate, complete, and consistent data sets, from device identifiers to clinical attributes. Misaligned product information is among the leading causes of submission delays and rejections.

Efficiency starts with aligning to international standards. By structuring product content around the requirements of globally recognized frameworks like that of the GS1 organization, companies can reuse data across multiple databases. Standardized attributes provide a consistent foundation for submissions – whether they are uploaded to the FDA's GUDID, Europe's EUDAMED, or systems in many other markets. Global standards help turning regulatory complexity into a repeatable, manageable process.

4.4. Common pitfalls and how to avoid them

Even well-prepared MedTech companies stumble when navigating global UDI compliance. The most frequent pitfalls are strikingly consistent: preparation left too late, product content scattered across systems leading to no Single Source of Truth, incomplete or missing attributes, miusunderstanding of UDI database regulatory and technical rules, delayed updates, and workflows that fail to align across departments. Each of these issues creates risk – whether in the form of rejected submissions, costly rework, or delayed market entry.

Summary of Implementation steps



05.

osapiens for Medical Device's capabilities – enabling digital compliance

Global compliance should no longer be a matter of fragmented local spreadsheets and manual workarounds. Regulators expect structured, complete, validated, and machine-readable product data. osapiens for Medical Devices (BYRD Health), provides MedTech companies with a centralized platform to transform UDI compliance into a scalable, digital process. The system consolidates product data into a single source of truth, ensuring consistency across multiple markets while reducing manual effort and the risk of errors.

5.1. Centralized product content management

osapiens for Medical Devices (BYRD Health) enables teams to manage all product content from one central location. Data from ERP, PLM, and marketing systems is harmonized. This single source of truth simplifies updates, approvals, and cross-market publication.

> "At **osapiens,** we combine technical capability with regulatory insight. Our **involvement in GS1** initiatives globally and MedTech expert groups allows us to **anticipate regulatory shifts and incorporate them directly into our platform."**
>
> LIONEL TUSSAU
> *Head of Healthcare at BYRD Health*

5.2. Automated data exchange through system-to-system connections and web-based interfaces

Manual uploads are slow, error-prone, and increasingly incompatible with today's regulatory demands. osapiens for Medical Devices (BYRD Health) replaces them with automated system-to-system connections that integrate directly with global UDI databases. For quick updates, user-friendly web interfaces provide flexible access. At the core is a single source of truth: manufacturers enrich and maintain product content centrally, then publish it to multiple regulatory authorities and industry partners at the push of a button.

5.3. Direct integration with global regulatory databases

osapiens for Medical Devices (BYRD Health) connects directly to leading UDI registries. This direct integration ensures that product content submissions are accurate, validated, and compliant with the specific requirements of each market, among others:

- **USA:** The FDA's Global Unique Device Identification Database (GUDID)
- **EU:** The European Commission's EUDAMED database
- **Australia:** The Australian Unique Device Identification Database (AusUDID)
- **Switzerland:** The Swiss UDI database (swissdamed, planned)

5.4. Connectivity with the Global Data Synchronization Network (GDSN)

Compliance does not end with regulators. Hospitals, group purchasing organizations, and distributors demand the same level of product transparency and accuracy as authorities do. With osapiens for Medical Devices (BYRD Health) , MedTech manufacturers gain direct access to the Global Data Synchronization Network (GDSN), ensuring that validated product content flows seamlessly not only to authorities like EUDAMED, GUDID, and other UDI databases but also to customers and supply chain partners worldwide.

Once product content is published in osapiens for Medical Devices (BYRD Health) , it can be automatically synchronized across more than 40 certified GDSN data pools worldwide – driving a global distribution of data. This continuous synchronization ensures that hospitals, group purchasing organizations, and regulators alike receive up-to-date, quality-checked information – without duplicate effort or manual uploads.

5.5. Built-in data validation to ensure accurate product content

Accuracy is non-negotiable. Errors in UDI submissions can lead to rejections by regulatory bodies that lead to costly delays. osapiens for Medical Devices (BYRD Health) provides built-in validation at every step, checking regulator-specific attributes, formats, and highlighting missing or inconsistent information before submission. This proactive control mechanism ensures data integrity, mitigates regulatory risk, and prevents downstream corrections.

Likewise, hospitals as well as group purchasing organizations increasingly rely on complete, high-quality, and continuously updated product content to optimize their processes. Validated product information accelerates procurement, reduces returns, and lays the foundation for digital clinical documentation. Standardized classification (like eClass) simplifies the identification of substitute products, while accurate logistics data ensures electronic goods receipt.

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5.6. Integration with internal systems

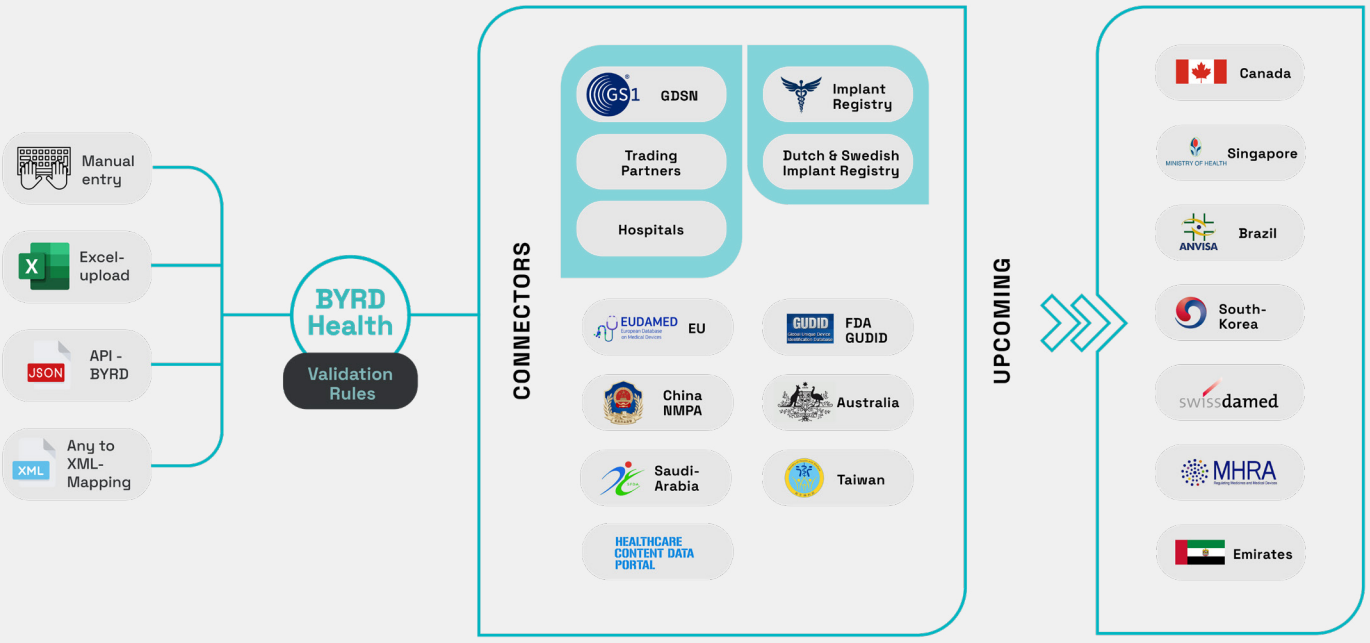
Regulatory compliance cannot operate in isolation. osapiens for Medical Devices (BYRD Health) integrates directly with leading PLMs (PTC Windchill), ERP and PIMs (Informatica) or other internal systems, consolidating product data from quality, regulatory, logistics and finance into a single source of truth. Internal attributes can be automatically mapped to healthcare-specific standards, enriched, and validated before publication. This unified dataset ensures that regulatory, quality, and operations teams all work from the same reliable information. Seamless synchronization eliminates duplication, removes manual handovers, and aligns compliance with commercial and operational workflows, making accurate, validated product content immediately available for regulatory submissions.

5.7. Real-time dashboards and compliance reporting for full transparency and audit readiness

Audit readiness requires transparency. osapiens for Medical Devices (BYRD Health) offers real-time dashboards that track submission status, compliance deadlines, and market coverage. Teams can track progress, identify bottlenecks, and generate reports. With a single view of global compliance, decision-makers gain control over risks and timelines.

> **"Many manufacturers underestimate the effort required to translate ERP attributes into healthcare-specific standards early on .** When companies wait until regulatory deadlines, they risk operational bottlenecks and costly duplication."
>
> LIONEL TUSSAU
> *Head of Healthcare at BYRD Health*

osapiens HUB for Medical Devices (BYRD Health)



06.

Strategic guidance – staying compliant globally

Global UDI compliance is no longer optional – it is a strategic necessity. Markets evolve constantly. Regulatory frameworks change. Authorities add new requirements, databases, and reporting obligations. For MedTech companies, staying compliant globally is a complex, ongoing task. Technology alone is not enough. Companies need strategic guidance, expert insight, and practical tools to navigate these challenges. osapiens for Medical Devices (BYRD Health) delivers all three.

> **"Our User Groups are designed to turn complex regulatory requirements into actionable insights for MedTech professionals.** By meeting every six weeks, participants share knowledge and experiences, creating a collective expertise no single company could achieve on its own."
>
> LIONEL TUSSAU
> *Head of Healthcare at BYRD Health*

6.1. Leverage of expert advisory services

Regulatory requirements vary across regions and can change at short notice. osapiens for Medical Devices (BYRD Health) offers dedicated advisory services that translate global UDI regulations into actionable steps for MedTech companies. Experienced consultants work closely with regulatory and operational teams to anticipate changes, reduce errors, and streamline submissions across multiple jurisdictions. They help to design workflows that comply with both local and international standards.

By embedding compliance into daily operations rather than treating it as a one-off task, osapiens for Medical Devices (BYRD Health) 's specialists help manufacturers avoid delays, prevent costly mistakes, and build sustainable, scalable compliance strategies.

6.2. Access to the exclusive osapiens User Groups

osapiens for Medical Devices (BYRD Health) users benefit from an invite-only community that meets every six weeks. These sessions bring together healthcare professionals from across global markets, providing early insights on UDI updates, practical use cases, and emerging regulatory challenges. The meetings create a platform to share experiences and learn from peers, benchmark approaches across regions, learn best practices across markets, and discuss strategies for operationalizing compliance.

6.3. Minimizing regulatory risks through proactive data governance

Inconsistent, incomplete, or outdated product data ranks among the biggest risks in global UDI compliance. For MedTech companies navigating multiple UDI systems, a single error can trigger submission rejections or delayed approvals. osapiens for Medical Devices (BYRD Health) helps manufacturers in centralizing product information, standardizing attributes, and automating validation workflows.

Proactive data governance does more than reduce submission errors. It strengthens internal quality assurance, enables teams to track data lineage, identify gaps, and correct discrepancies well before external audits. In practice, osapiens for Medical Devices (BYRD Health) transforms compliance from a reactive, check-box activity into a controlled, auditable, and reliable process.

6.4. Learning from leading healthcare manufacturers through proven best practices

Global UDI compliance succeeds when best practices are applied consistently. osapiens for Medical Devices (BYRD Health) captures workflows, system integrations, and multi-market submission strategies from top MedTech manufacturers, turning experience into actionable guidance.

By learning from industry leaders, MedTech manufacturers avoid reinventing the wheel and gain the confidence to scale compliance across markets. Leveraging community knowledge through experienced networks like osapiens for Medical Devices (BYRD Health), those experts are closely connected with regulators, trade associations, and issuing entities such as GS1, provide medical device manufacturers with a unique visibility into evolving requirements. By utilizing community expertise, companies stay ahead of regulatory changes.

6.5. Strategic support for aligning internal processes across global regulatory requirements

Global UDI compliance cuts across the entire organization – touching R&D, quality, regulatory affairs, labeling, supply chain, commercial, and operations. When these functions work in si-

los, the result is duplicated effort, inconsistent submissions, and elevated risk.

osapiens for Medical Devices (BYRD Health) helps manufacturers break down these silos by mapping end-to-end processes, identifying gaps, and harmonizing workflows across departments. Standardized practices ensure that requirements from different jurisdictions can be met simultaneously, without reinventing processes for each market.

The impact is measurable: fewer errors, time to market, and lower operational overhead. By aligning internal processes strategically, MedTech companies transform compliance from a fragmented obligation into a repeatable, scalable capability.

6.6. Guidance for planning, implementation, and adapting to regulatory changes

Global UDI regulations are anything but static. New rules emerge, databases are updated, and timelines shift – often with little advance notice. Companies that react too late face rushed submissions, higher error rates, and costly delays.

osapiens for Medical Devices (BYRD Health) equips manufacturers to stay ahead of these changes. Experts provide structured guidance for planning compliance programs, implementing regulatory updates efficiently, and adapting internal processes before deadlines hit. Instead of last-minute adjustments, companies build the capacity to respond systematically and predictably. The result: smooth transitions, fewer disruptions, and a compliance framework that stays resilient even as regulations evolve.

6.7. Scalable solutions designed to meet the needs of regional and global compliance

Compliance requirements differ widely – not only across markets, but also between manufacturers. A start-up with a niche device portfolio faces different challenges than a global enterprise managing thousands of UDIs.

osapiens for Medical Devices (BYRD Health) addresses this diversity with scalable solutions that adapt to the size, scope, and maturity of each company. The modular platform and advisory services support everything from regional product launches to multi-country rollouts and full global operations.

This flexibility ensures that manufacturers can grow without outgrowing their compliance systems. Whether managing high-volume portfolios or a small number of specialized devices, companies maintain consistent, audit-ready processes across all markets.

The key to Global Compliance

Strategic guidance	User Groups, adapt to regulatory changes, proactive data governance
Expert insight	Professional services, share proven best practices, align internal processes
Practical tools	Scalable solution for local, regional and global needs

07.

UDI implementation strategies – from readiness to execution

> Manufacturers who validate data continuously gain control and predictability. It transforms compliance from a reactive, error-prone process into a repeatable, scalable workflow. Teams can focus on delivering products efficiently rather than firefighting last-minute issues."
>
> LIONEL TUSSAU
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7.1. Select and register with the appropriate issuing agency

UDI identifiers must be created using identifiers from accredited agencies such as GS1, Health Industry Business Communications Council (HIBCC), International Council for Commonality in Blood Banking Automation (ICCBBA), or the Informationsstelle für Arzneispezialitäten (IFA). While the FDA accredits issuing agencies for the US market, the same standards – primarily those of GS1 – are also recognized in the EU, UK, Australia, and many other countries. China's National Medical Device Administration (NMPA) – under the supervision of the State Administration for Merket Regulation (SAMR) – is phasing in their own national system and is also built on GS1 standards.

7.2. Update labeling and packaging processes

Regulators worldwide expect UDI to appear on device labels and packaging in both human-readable and machine-readable from Companies need to redesign packaging artwork and adapt manufacturing processes to ensure consistent UDI labeling across jurisdictions.

7.3. Align internal procedures across the lifecycle

UDI is not just a labeling task. It impacts regulatory affairs, quality management, supply chain, and IT. The European Medical Device Coordination Group (MDCG) stresses integration of UDI processes into Quality Management Systems, while the FDA requires embedding compliance into device master records. MedTech companies should establish cross-functional workflows so that product development, registration, and post-market surveillance use the same UDI data structures.

08.

Conclusion: The Countdown to compliance

8.1. Summary of key insights

Global UDI compliance is no longer a distant regulatory ambition. With frameworks in place across the United States, the European Union, China, Saudi Arabia, Australia, Turkey, Brazil or Switzerland, manufacturers face a fragmented but unavoidable set of obligations. Compliance requires far more than printing a barcode on a label. Companies must manage complete, validated product data, adapt packaging processes, and integrate business systems to support submissions to multiple national databases. Harmonization efforts exist through the IMDRF, but regional local interpretations remain a reality.

8.2. Importance of early preparation

The most successful MedTech manufacturers are those that treat UDI not as a late-stage labeling exercise, but as a strategic transformation project. Regulators enforce strict timelines, and the experience from the US and EU demonstrates that last-minute compliance leads to costly delays, rejected submissions, and fines or even loss of market access. Early preparation allows companies to align cross-functional teams, establish data governance, test and implement the IT integrations needed for sustainable compliance. With new deadlines approaching the countdown has already begun.

8.3. Achieving success: Engage with experts

osapiens for Medical Devices (BYRD Health) supports MedTech companies worldwide in turning regulatory compliance into a competitive advantage. Through centralized product content management, automated data exchange, and direct connectivity with regulatory databases, hospitals, and group purchasing organizations, osapiens for Medical Devices (BYRD Health) provides the digital backbone for efficient UDI compliance. Its advisory services and user groups create a trusted network for staying ahead of regulatory changes. For companies navigating the complexity of global requirements, engaging with osapiens for Medical Devices (BYRD Health) experts ensures not only compliance, but also readiness for future market dynamics.

UDI databases and regulators

- EUDAMED European Database on Medical Devices — EU
- GUDID Global Unique Device Identification Database — FDA GUDID
- China NMPA
- Australia
- Saudi-Arabia
- Taiwan
- HEALTHCARE CONTENT DATA PORTAL

Manage medical device and product data with ease, ensure compliance with global regulations (such as MDR/EUDAMED), and seamlessly share them with hospitals, purchasing groups, and marketplaces. The **osapiens for Medical Devices (BYRD Health)** ensures digital, automated, and quality-assured processes for the healthcare, medical and pharmaceutical sectors in a validated environment.

Unlock seamless compliance and product syndication with osapiens for Medical Devices (BYRD Health) – the ultimate solution to stay ahead in the medical device industry by managing data with ease, accuracy, and efficiency.

- Effortless Compliance: Ensure seamless adherence to global regulatory standards, including EUDAMED, GUDID, and many more, while maintaining a secure, validated environment.
- Seamless Syndication: Distribute high-quality product data across all channels to trading partners and customers via GDSN — all from one centralized platform.
- Process Efficiency: Automate complex processes and manage the entire product content lifecycle for maximum accuracy and reliability across the medical devices and healthcare sectors.
- Our renowned in-house experts are at the forefront of the industry, ensuring that your product data lifecycle is seamless, efficient and fully compliant. As such, we take on various leadership roles, such as co-chair of the „EUDAMED IT Expert Group“ at MedTech Europe. And as part of the GS1 Global Healthcare Leadership Team, we collaborate with regulators and top trade associations to keep you ahead of the curve in a rapidly evolving marketplace. Partner with us for expertise you can trust!

Power your compliance, streamline your operations, and accelerate your growth with osapiens for Medical Devices!

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At *USDM Life Sciences,* we empower life sciences organizations to drive innovation through intelligent operations. By integrating AI, automation, and digital quality systems, we help biotech, pharma, and medical device companies deliver transformative results. Trusted by global technology leaders and life sciences organizations alike, we ensure seamless alignment between compliance and cutting-edge innovation. With tailored solutions that evolve regulated tasks, we enable our customers to achieve measurable outcomes with agility and confidence.

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