GS1 Guide on Unique Device Identification (UDI) implementation in the USA and in the EU

This document aims at providing clarification to questions raised by the industry as well as implementation guidance on the use of GS1 standards.

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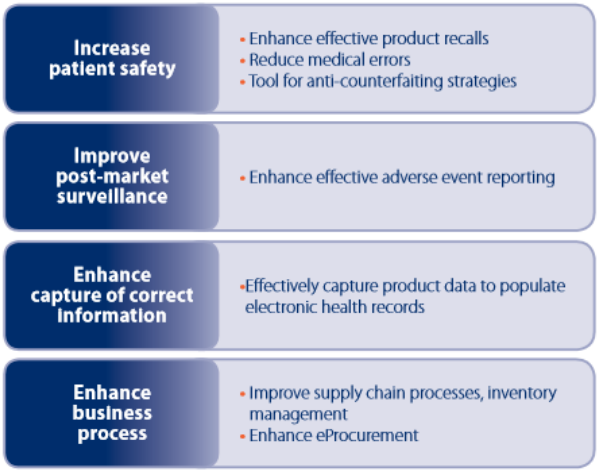
Executive Summary
Unique Device Identification (UDI) improves patient safety and healthcare business processes and will require significant implementation investments by manufacturers, providers and other healthcare organisations. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all healthcare stakeholders worldwide. The GS1 System of standards provides a global framework to identify, capture and share healthcare product information, thereby enabling a worldwide implementation of UDI.

The United States Food and Drug Administration (U.S. FDA), the European Commission and other regulators have made safety and integrity of the global healthcare supply chain a strategic priority by adopting legislation for Unique Device Identification for medical devices.

The successful implementation of UDI by all healthcare stakeholders from manufacturers to healthcare providers, will depend on several factors, including:

- Global reach – local deviations will limit the opportunities to leverage UDI data in a consistent manner, increasing cost and complexity and creating opportunity for error.
- Sector-wide reach – all stakeholders need to collaborate and integrate UDI into their processes and systems, including in healthcare systems to make a meaningful impact.
- Risk-based approach – the diversity of medical devices needs to be considered.
- Standards-based approach - proprietary methods of capturing and exchanging information will limit seamless connectivity, increasing cost and complexity.

The challenge: Unambiguous identification of medical devices and rapid access to device related information



"Current device identification is a mess. Different manufacturers use different standards in different ways if they use anything at all. Distributors apply their own. Hospitals apply their own. And we just sort of cascade into this series of events which means that we can't find devices."

Jay Crowley, former Senior Adviser for patient safety at the US FDA CDRH
FDA UDI Public Workshop on Feb. 12, 2009.

The U.S. FDA published its Final Rule on UDI on 24 September 2013. The European Commission has also developed UDI requirements, that are part of the EU Medical Devices Regulation (MDR) and the In-Vitro Diagnostics Regulation (IVDR) and will be further detailed in future Implementing or Delegated Acts. Other countries are also looking into UDI regulations (e.g. China, Brazil, South Korea, Saudi-Arabia,).

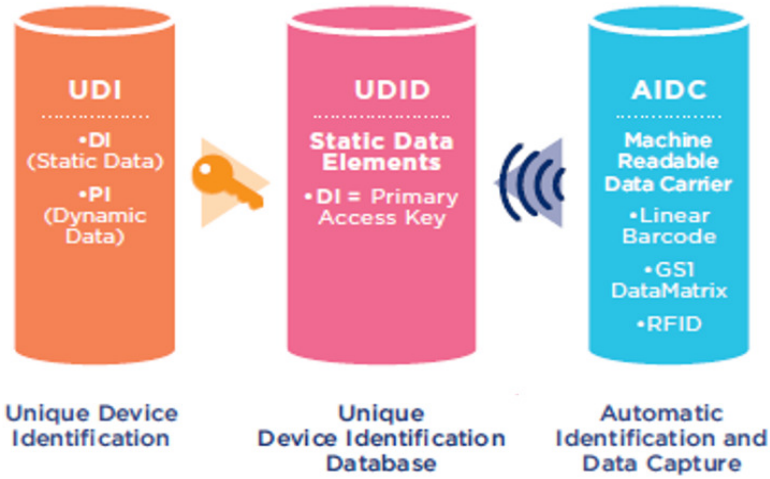
The solution: The Unique Device Identification (UDI) system

What is the UDI system?

The UDI system is defined, by the International Medical Device Regulators Forum (IMDRF) in the UDI Guidance, as "the framework for:

1) UDI production,
2) UDI application on the label or on the device, and
3) UDI Database (UDID) fundamental contents"

The word "unique" does not imply that every single device needs to have a serial number.



The UDI system at a glance

Traceability and storage in the EU

For Class III implantable devices (this scope might be expanded through an implementing act), the economic operators will also have to store the UDI code. Health institutions / health professional will have to store the UDI for Class III implantable devices.

Economic operators[1] shall be able to identify any operators and health institutions to whom they have directly supplied a device and any operator who has directly supplied them with a device: a one-up-one-down traceability model.

The UDI shall be included in the field safety notice for reporting serious incidents and field safety corrective actions.

Who is involved in the implementation of the UDI system?

The economic operator responsible for complying with the UDI requirements can be different in the USA and in the EU.

According to the U.S. FDA Rule, the "labeller" of medical devices is responsible and is defined as any person who causes a label to be:

- applied to a device with the intent that the device will be commercially distributed; or
- replaced or modified with the intent that the device will be commercially distributed.

In the EU, the "legal manufacturer" of the device is responsible and is defined as "the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark". This definition aligns with the GS1 definition of the "brand owner".

It is important to clarify that the UDI requirements apply to the labeller/legal manufacturer located outside of the USA or the EU – i.e. European Member States plus potentially countries of the EEA (e.g. Switzerland, Norway, Iceland, Liechtenstein). Indeed, the requirements apply to any medical devices placed on the market, in the USA or in the EU, regardless of where the devices are manufactured.

The full UDI implementation will always require other stakeholders to integrate UDI in their respective systems.

How to create a UDI code?

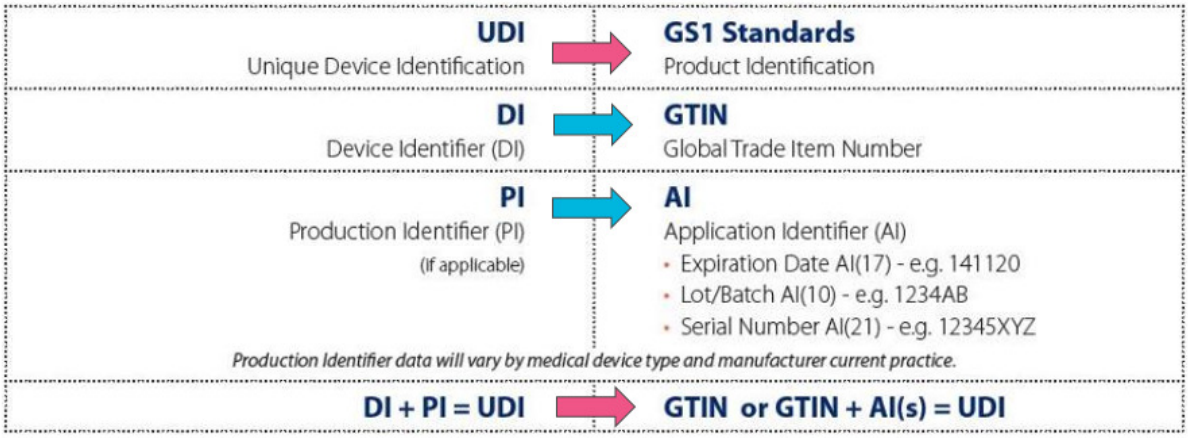
A UDI code aims at unambiguous identification of a specific medical device. To ensure a globally standardized and harmonized system, the UDI code must be issued under the rules of a U.S. FDA-accredited issuing agency or an EU-accredited assigning agency, which includes GS1.

The UDI code is a unique, alphanumeric code, which consists of two parts:

- a Device Identifier (DI): a fixed code specific to a version or model of a device. It is also the identifier used to access the UDI Database. The GS1 Global Trade Item Number (GTIN) enables this aspect of the UDI.
- Production Identifiers (PI): a variable code related to production data of the device, such as lot/batch number, expiry date, manufacturing date, etc. All the

[1] Under the EU MDR "economic operator means a manufacturer, an authorised representative, an importer, a distributor or the person"

production information mentioned on the label or the package of the device must be included in the PI, in both human and machine readable format. The GS1 Application Identifiers (AIs) enable this aspect.
The human readable interpretation[2] (HRI) rules followed are defined by the Issuing Agency.



How to apply a UDI code?

Once generated, each UDI code must be applied in both human and machine readable form. The UDI code should be on each applicable packaging level, from the unit of use to the highest package level. Each designated packaging level that is a trade item must have its own DI (GTIN). Logistics units[3] are exempt.
"Direct marking" is required for certain devices, which are intended to be reused or reprocessed. The labeler/manufacturer must determine whether their products fall under Direct Marking criteria or whether their products meet an existing exception.

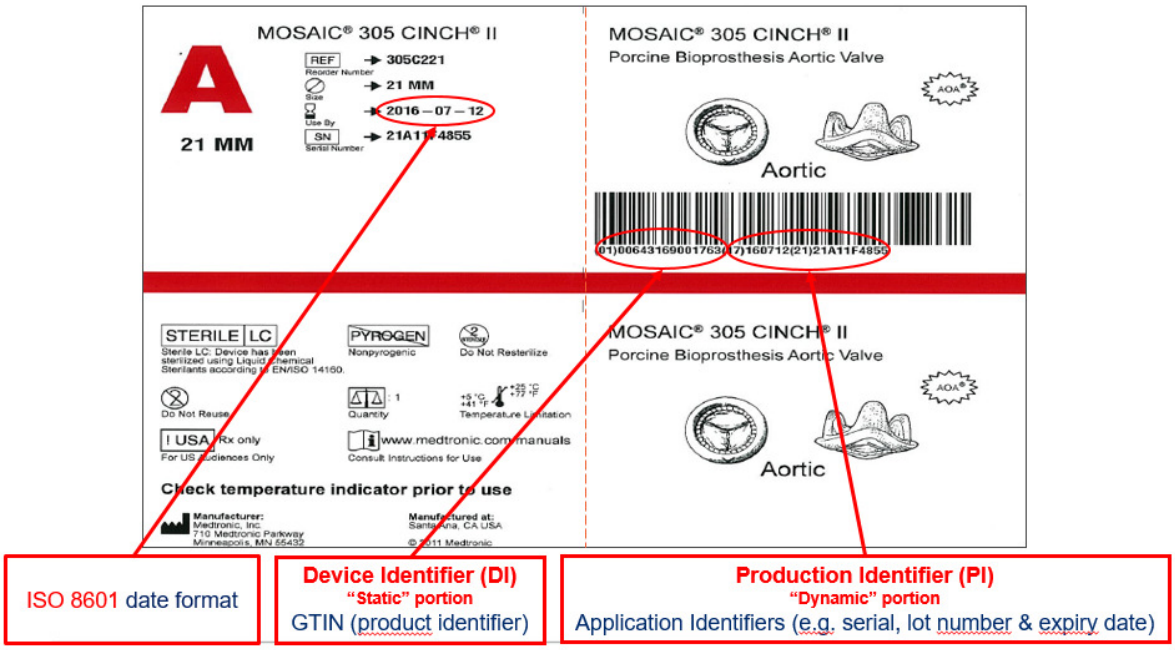
Specifications vary by the issuing agency. It is important to understand and to follow the GS1 GTIN Management Rules to ensure the accurate allocation and application of the UDI code.

NOTE: GTINs below for illustration only

Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
00857674002010	10857674002017	40857674002018

[2] Characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The human readable interpretation is a one-to-one illustration of the encoded data.
[3] Under the GS1 General Specifications, a "logistic unit is an item of any composition established for transport and/or storage which needs to be managed through the supply chain. Logistic units take many forms, a single box containing a limited number of products, a pallet of multiple products, or an intermodal container containing multiple pallets."

The UDI requirements in the USA and in the EU do not explicitly require barcode verification. However, the GS1 General Specifications require ISO/IEC based barcode print quality verification to help ensure readability throughout the supply chain.



Example of a US compliant UDI label using GS1 standards

What are the main difference between the USA and the EU requirements for AIDC?

- Basic-UDI-DI: is to be used in the EU as the primary identifier of the device model, assigned at the device unit of use. It is not applied on the devices. It is the main key for records in the UDI Database and is referenced in relevant certificates and EU declarations of conformity. At the time of the development of this paper, it is still not clear how the definition of the Basic-UDI-DI will be interpreted ("model" versus "unit of use"). Guidance for implementation will be released. That Guidance and the resultant interpretation of "Basic-UDI-DI" will determine how the GS1 System is applied in this regard.

- For single use devices of Class I and IIa packaged and labelled individually in the EU: the barcode can be applied on the next higher packaging containing several individually packaged devices (applies to all classes in the USA). This does not apply when the healthcare provider does not have access to the higher level of device packaging (e.g. devices used for home care).

- Direct marking on the device for reusable devices, with some exemptions, both in the USA and in the EU. The difference is that the U.S. allows the bar code or the HRI or both to be direct marked, but does not require both, whereas the EU requires both the bar code and the HRI.

- Specific rules apply to for implantable devices, kits, systems and procedure packs, configurable devices, device software in the USA and in the EU.

- In the EU, in cases of significant space constraints, the barcode format (not the HRI) shall be favoured unless the device is intended to be used outside of health institutions (e.g. devices used for home care).

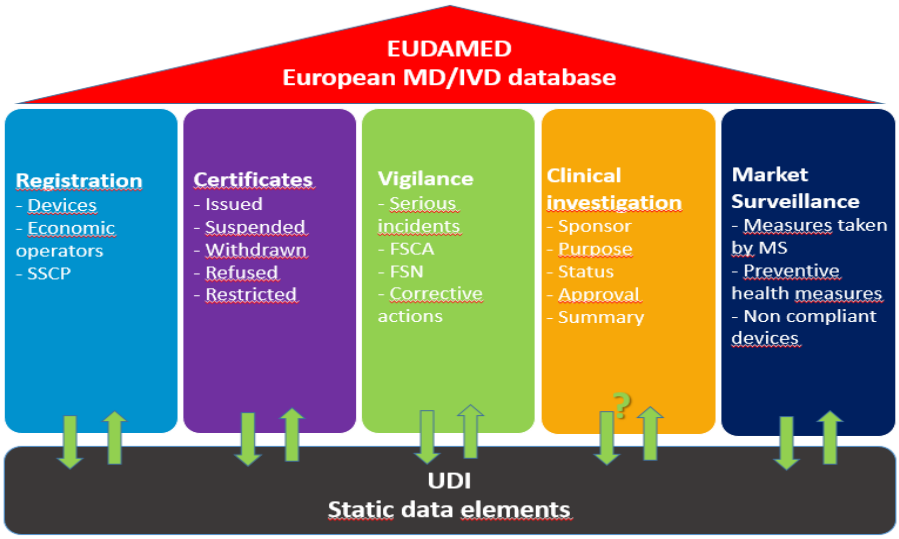
- In the EU, the serial number is required for active implants. Serial number or lot number is allowed for other implants.

- On the device package label, there is no mandated date format in the EU, whereas the U.S. FDA has mandated a specific date format of the ISO standard 8601 (i.e., YYYY-MM-DD). For the HRI, the text that represents the data encoded in the barcode, the rule of the issuing agency will apply both in the EU and in the USA (i.e., for GS1 standards: YYMMDD).

How to submit data to the UDI Database?

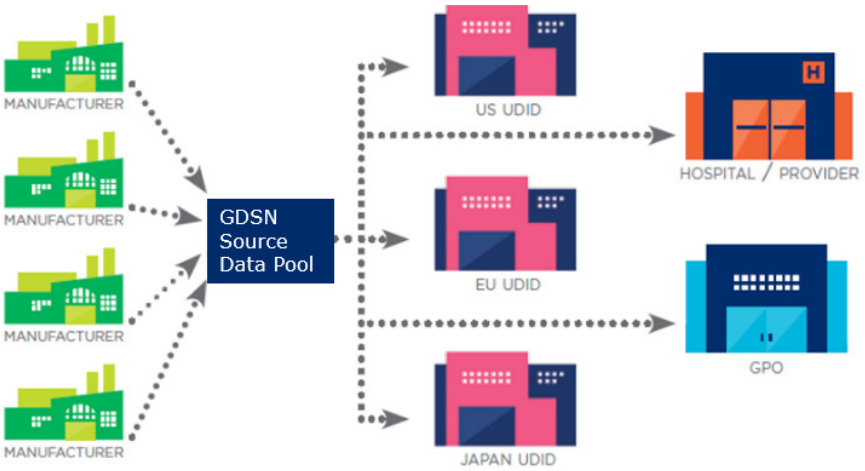
Based on information available at the time of the development of this paper, it is expected that the structure of the UDI database in the European Union (named MDR EUDAMED) will be different to the one of the U.S. FDA UDI database (named GUDID). The design aspects such as the data reference table, data element definitions, machine-to-machine protocol (HL7 SPL in the USA) and nomenclature (GMDN in the USA) are yet to be defined by the EU Commission.

The EUDAMED system and work-flow processes are more extensive and go far beyond UDI as shown in the diagram below. The UDI Module will be closely connected to the Device Registration Module. UDI data registration will be a prerequisite for device registration.



MDR EUDAMED structure

The GS1 Global Data Synchronisation Network (GDSN) may be leveraged to register data in the U.S. FDA GUDID via the certified Data Pools which perform as a third party data provider. GS1 with input from the community it supports, will draft the proper guidance as soon as the relevant information is available from the EU to enable the same for Eudamed.



GS1 Global Data Synchronisation Network

Completeness and accuracy of product data is the responsibility of the legal manufacturer in the EU. Each manufacturer should have an internal process to manage the data required by the regulator. This includes the following:

- Data quality checks and procedures
- Data management process and policies
- Enterprise-wide data governance policies
- Roles and responsibilities which outline who has the authority to create, modify and approve the data

Therefore, GS1 recommends that every manufacturer employ proper internal data management and quality procedures.
For more information on data quality refer the Data Quality section of the GS1 website (http://www.gs1.org/data-quality) as well as sections 1.5 – 1.9 of the GDSN guide for the GUDID (http://www.gs1.org/healthcare/share-data-gdsn).

What is the timeline to become UDI compliant?

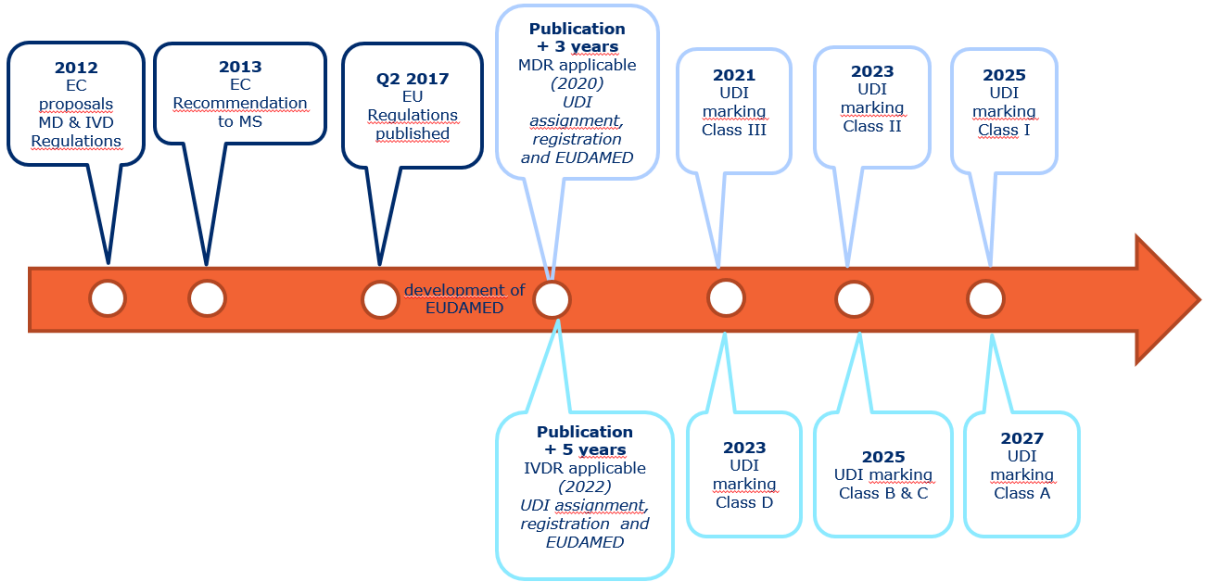
The UDI system will go into effect in stages over a period of several years to ensure a smooth implementation and to spread the costs and burdens of implementation over time.

When Direct Marking is required, each deadline is given a 2 years extension for compliance, both in the US and in the EU.

In the USA, devices already on the market are exempted until the end of their life cycle. In the EU, devices already on the market are exempted until 5 years after the date of application of the Regulation (i.e. 2022). After that deadline, they must be removed from the market or comply with the UDI requirements.

Compliance date	U.S. FDA UDI rule
24 Sept. 2014	Class III Medical Devices and Devices under the Public Health Service Act (PHS Act) : UDI Labelling and GUDID Submission
24 Sept. 2015	Implantable, Life-Supporting, and Life-Sustaining Devices: UDI Labelling and GUDID Submission
24 Sept. 2016	Rest of Class II: UDI Labelling and GUDID Submission
24 Sept. 2017	Soft Contact Lens given a Labelling and GUDID UDI compliance extension
24 Sept. 2018	Class I and all other devices: UDI Labelling and GUDID Submission

Deadlines in the EU are subject to change depending on the MDR EUDAMED functioning.



What are Class I, Class II, and Class III devices?

Medical devices are classified based on the level of control necessary to assure the safety and effectiveness of the device. It is very important that the labeller/legal manufacturer assess the classification of each device in order to define the relevant compliance timeframe.

In the EU, no ad-hoc exemptions are foreseen whereas specific request can be submitted to the U.S. FDA.

How does GS1 support the implementation of UDI?

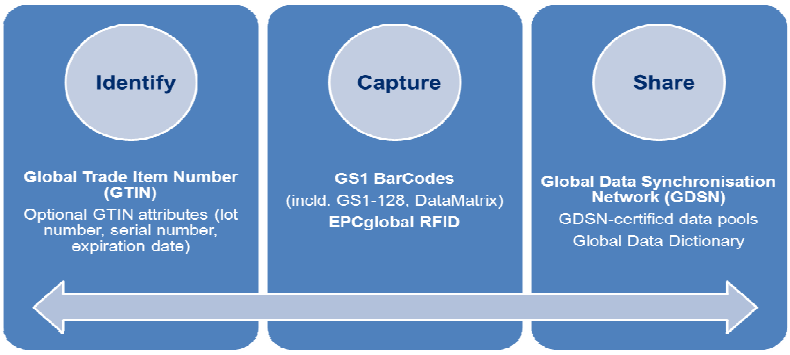
GS1 has over 100 GS1 Member Organisations and 2,000 employees worldwide providing support to users on how to implement UDI in their local language and understanding the local situation.

GS1 has successfully managed communities of users from various sectors for over 40 years. GS1 Healthcare, the global Healthcare user group, has provided a neutral forum for the last eleven years for all healthcare supply chain stakeholders to meet

and develop the necessary standards. The Global Standards Management Process (GSMP) ensures a truly user-driven, controlled process to develop standards.

The GS1 System of Standards enables all stakeholders to efficiently and effectively meet UDI requirements by ensuring interoperability and compatibility within an organisation, between organisations and across borders. A single standard will ultimately accelerate implementation and increase compliance to the UDI regulations while reducing cost.

1. Global – GS1 Standards ensure globally unique identification and enable cross-border compatibility of supply chain solutions.
2. Robust – Today, in various sectors, over 6 billion transactions per day are enabled by GS1 Standards, demonstrating its robustness.
3. Multi-sector – Using the same standard to identify and trace healthcare and non-healthcare items ensures compatibility for healthcare stakeholders sourcing a wide variety of items.
4. User-generated – GS1 Standards are built and maintained collaboratively by volunteers from across the world with stakeholders representing every part of the supply chain.
5. Scalable – GS1 Standards meet the needs of a small rural hospital as well as a multi-national supplier. Many healthcare manufacturers have already invested strongly in the implementation of GS1 Standards and can leverage that for further roll out.



Standardised product identifiers, such as the GTIN, provide unambiguous identification for both UDI and the supply chain leveraging a single investment in standardisation worldwide. The GDSN provides as single point of connection for both regulatory and customer requirements for device-related information.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.
GS1 Healthcare members include over 70 leading Healthcare organisations,
For more information about GS1 Healthcare, please visit http://www.gs1.org/healthcare.