Czech Republic

A medical device manufacturer's experience of UDI and its implementation

Challenge

Although it may seem that Unique Device Identification (UDI) only means the addition of a barcode on a label and the entry of certain information into the UDI local database, LINET found the implementation of UDI to be a very complex task requiring money, equipment, people and time.

Approach

The main objective of UDI implementation must be a process that is sufficiently robust and ensures that each medical device is clearly identified, and that correct information will be entered at the correct time into a relevant UDI database. This process must be integrated into the manufacturer's quality management system.

Creating a UDI process should involve almost all departments

To have a UDI system in place is a proactive advantage for manufacturers

UDI helps with traceability throughout the supply chain

UDI is used globally in communication with national authorities

LINET spol. s r.o. is a major European manufacturer of hospital and nursing beds. The company's portfolio includes solutions designed for intensive care, products for regular in-bed treatment and also specialised beds for old people's homes and long-term care facilities. The LINET range also includes a wide range of accessories such as anti-pressure ulcer mattresses, mobile equipment, and healthcare furniture.

LINET headquarters, as well as its production plant, continue to be based in Želevčice u Slaného in the Czech Republic, where it has been located since its establishment in 1990. The plant manufactures around 60,000 hospital beds per year, the vast majority of which are exported to more than one hundred countries worldwide. LINET employs around 1,000 staff. Since 2011, LINET spol. s r.o. has been a division of the multinational holding organisation LINET Group SE, with registered offices in the Netherlands.

Jan Štěrba

Unique Device Identification of medical devices

UDI (Unique Device Identification) is a unique, globally-used standard for identifying medical devices along a healthcare provider's entire supply chain and for the lifetime of a product. The aim is to increase patient safety and optimise healthcare by facilitating the traceability of medical devices, such as in the case of withdrawal of products from circulation.

The first non-binding document setting out the framework and rules of the system was published in 2011 by a voluntary international group, Global Harmonisation Task Force (GHTF) within the IMDRF (International Medical Device Regulators Forum), comprising representatives of national authorities and trade associations in Europe, USA, Canada, Japan and Australia.

Broadly, the UDI system consists of:

- Creating UDI using a globally accepted standard.
- Labelling product(s) and/or product(s) packaging using UDI.
- Entering information into UDI public databases (UDID).

The UDI designation must be placed on a product in a format legible to humans, with information that can be decoded by a machine, using barcodes, for example, UDI consists of two parts: a device identifier (DI) and a production identifier (PI), which make up unique device identification (UDI). A DI is a unique numeric or alphanumeric code identifying a medical device model and it is also used as an access key to information stored in a UDI database. It is a static code, generated only once for a specific device model. The PI is a numeric or alphanumeric code identifying a device unit in production. The PI may have different types depending on the type of equipment produced (e.g. a serial number, date of manufacture, expiry date, production batch number, software version, etc.). This is known as the 'dynamic' part of UDI.

Expansion of UDI to new markets

Currently, the UDI system has only been implemented in the USA. Since 2013, the FDA (Food and Drug Administration) government agency has required UDI to be assigned to certain medical devices by entering its information into the GUDID database (Global UDID). Other jurisdictions expecting to initiate the use of the UDI system in the coming years are the European Union, Russia, China, Japan, Australia, Brazil, South Korea and Argentina.

What is expected from a medical device manufacturer?

A medical device manufacturer who puts, or plans to put, a medical device onto the market where UDI is required, must create and maintain a globally unique UDI for its medical devices. The manufacturer is responsible for understanding the requirements of national authorities, and other relevant entities, in respect of the correct designation of medical devices using UDI in a machine-readable format that is also legible to humans. The manufacturer will also be responsible for submitting and updating information in the UDID.

A leading global hospital bed manufacturer's experience

Does it sound simple? Unfortunately, it is not. Immediately after initial analysis, staff at LINET realised the extent and consequences of the UDI system. Although it may seem that UDI only means the addition of a barcode on a label and the entry of certain information into the UDI local database, the implementation of UDI is a very complex task requiring money, equipment, people and time. The author therefore recommends that any producer reading this article and planning to introduce the UDI system (e.g. because of preparations for the new EU Regulation 2017/745) start well in advance and not underestimate the preparation needed.

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Selection of a strategic partner

One of the first necessary tasks is also the selection of an issuing agency. This agency is an approved organisation that will operate the system for allocating unique device identification in accordance with the requirements in its area of jurisdiction. At present, the following three entities are globally recognised: GS1, HIBCC and ICCBBA. As the UDI system spreads globally, it is expected that other authorised entities will be established and appointed, for example, only for local markets. Before any selection is made, it must be emphasised that the authority will become a strategic partner and ask key questions. Are you already using any existing identifiers from any of these institutions (e.g., GTIN from GS1)? What standard is recognised by the market where you plan to sell? Do customers expect a specific standard? What services do you expect? LINET selected GS1 Czech Republic as its strategic partner to work on these areas.

Selection of an optimal method

Depending on the availability of resources, the size of the company and the portfolio, the manufacturer must also determine in what manner it wants to implement UDI requirements. This can be by its own means, in cooperation with an expert in the given field, or by fully outsourcing UDI implementation. Each option has its advantages and disadvantages. However, keep in mind that non-transferable responsibility for the UDI system is still associated exclusively with the manufacturer. This also applies to OBL manufacturers (Own Brand Labeller—an entity that introduces another manufacturer's medical devices to the market under its own name).

Another key decision is how the manufacturer will enter data into the UDI database. If it has a small portfolio of products and releases its product, for example, in only one country that has its own UDI database, it may enter the information into the UDI system manually via a web interface[1]. However, for global suppliers of medical devices, this activity should be automated using an appropriate software solution. Although software will reduce the risk of potential errors, its implementation is more expensive and requires thorough verification and validation of the given tool.

It is clear from the above that preparing and creating a UDI process should involve almost all departments governed by the quality management system (again, depending on the size of the company and diversity of the product portfolio). The project should ensure all of the above but must also provide the following at a minimum—integration of UDI into the existing information system, a single source of UDI information, and installation, testing and validation of the software for printing barcodes. Furthermore, staff require training, labels need to be modified and UDI added. Equipment for printing and verifying UDI on the labels must also be purchased and installed, and the requirements in respect of record maintenance and reporting should be put into practice. After the project is complete, it has to provide continuity for any planned work, operations and maintenance associated with the equipment for printing operations, software maintenance and any training necessary for maintaining the information system.

Readiness for implementation of the European legislation

LINET initiated UDI implementation in 2015 in conjunction with the requirements of the US market. In the same year, consultation with GS1 Czech Republic staff took place which provided excellent support in the planned introduction of UDI. Almost a year later, LINET was successfully registered in the American UDI database (GUDID) and launched the first products on the US market with the identification required. Although this requirement was not imposed on any other country at the time, the company decided to apply the new version of its identification label to its entire portfolio, not only to products designated for the US market. LINET therefore has a head start in preparing for compliance with the requirements of the new European regulation for medical devices in 2020.

[1] In the future under MDR (new EU Regulations for medical devices), this will depend on the phase of implementation.

Next steps

LINET uses for submission of relevant information in GUDID web interface only, because its current portfolio for US market is limited and it can be handled manually without additional costs. As a next step to adapt to the new UDI requirements of other jurisdictions (EU, KSA, ...) the company is preparing an automatic solution for the submission of relevant information to one data pool (e.g. Global Data Synchronisation Network (GDSN) certified data pool). This data can then be sent to individual databases or can be available via subscription by customers as well. Despite higher initial costs, this solution will help to improve current process, limit human errors, save time and satisfy national authorities and customers.

To have a UDI system in place is also a proactive advantage for manufacturers during communication with hospitals or other healthcare providers, because although UDI system is not globally required by law (yet), many customers are requiring it as part of tender specifications.

Benefits

UDI helps with traceability throughout the distribution supply chain – from manufacturer to customer. This identification number is used globally in communication with national authorities e.g. in case of adverse event or other undesired incident and helps manufacturers to trace medical devices.

Conclusion

The UDI system is being developed to facilitate adequate device identification through distribution and use on patients. This system is newly forming across various regulatory jurisdictions at varying levels of system maturity. When the UDI system is fully implemented, the labels of most devices will include a UDI in human and machine-readable format. In addition, globally harmonised meta-data about devices will be available in UDIDs as populated by regulated entities.

It's therefore key that if you work in this area, you begin work on compliance as soon as you can, to ensure you're in the best position possible to meet with requirements.

About the author

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Jan has got a practical experience with development and conformity assessment of medical devices and implementation and maintaining of Quality Management System mainly in accordance with ISO 13485:2016, ISO 9001:2015, FDA and MDSAP requirements. He was involved in preparation for UDI compliance with U.S. Federal law. Now he manages preparation of company compliance with new European Medical Device Regulation 2017/745.

Jan is an active member of Czech association of suppliers of medical devices (CzechMed), where he cooperates on developing of national medical devices regulation and its harmonization with European legislation.

He holds Masters degree in biomedical engineering.

About the organisation

LINET spol. s r.o. is Europe's largest producer of innovative, high-quality healthcare beds, antidecubitus mattresses, furniture, and comprehensive solutions for hospital, nursing care facilities and gynecological practices. LINET headquarters, as well as its production plant, is based in Želevčice u Slaného in Czech Republic, where it has been located since its establishment in 1990. The plant manufactures around 60,000 hospital beds per year, the vast majority of which are intended for export to more than one hundred countries worldwide. www.linet.com