Agence nationale de sécurité du médicament et des produits de santé

Vigilance related of medical device (MD) or in vitro diagnostic medical devices (IVD): Q&A on reading anomalies of the UDI carrier

What is a UDI carrier?

The UDI (Unique Device Identifier) is a series of numbers or letters created according to an international identification and coding standard. It consists of a UDI-DI (Device Identifier) and a UDI-PI (Production Identifier). AIDC (Automatic Identification and Data Capture) is a technology used to capture data automatically. The UDI carrier consists of the AIDC (machine-readable) and, where applicable, its human-readable interpretation. UDI carriers include one-dimensional or linear barcodes, two-dimensional barcodes/QR codes, and radiofrequency identifiers (RFID). The UDI carrier is affixed to the label or directly to the device itself and to all higher levels of packaging of the device. This applies to medical devices (MD) and in vitro diagnostic medical devices (IVD).

What is the purpose of an UDI carrier?

Reading an UDI carrier, as it enables the precise identification of products, is particularly useful for the computerized stock management of devices, their identification (for example, by a medical laboratory automation system), or even the traceability of implantable devices.

Some devices do not have a UDI carrier, is that normal?

The UDI is a requirement introduced by the European Medical Device Regulations ((EU) 2017/745 and (EU) 2017/746): the assignment of a UDI code is mandatory from the launching of the product on the market. However, there are exceptions: custom-made devices, investigational devices, and in vitro diagnostic medical devices (IVD) undergoing performance studies (prior to CE marking).
The UDI carrier should be present on CE-marked devices according to these two European regulations. A timeline for affixing UDI codes on packaging and devices is accepted in the regulations, according to the following schedule:

- For medical devices (MD): until 26-May-2021 for implantable MDs and class III MDs, until 26-May-2023 for class IIa and IIb MDs, and until 26-May-2025 for class I MDs.
- For in vitro diagnostic medical devices (IVD): until 26-May-2023 for class D IVDs, until 26-May-2025 for class B and C IVDs, and until 26-May-2027 for class A IVDs.

Note: It is the date the devices are placed on the market that should be considered, not the date of purchase or use.
Devices that are CE-marked according to the repealed Directives 93/42/EEC and 98/79/EC do not have an UDI (and subsequently, no UDI carrier).

What types of events can occur when reading an UDI carrier with a barcode reader or scanner system?

Here are some examples of reported events: absence of the UDI carrier when it should be present, absence of the human-readable interpretation (clear text), non-compliance with international identification and coding standards, mismatch between the clear text information and the AIDC information, or the unreadability of an AIDC by a barcode reader or scanner system.

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Are these events covered by vigilance?

Example outside of vigilance
If the event involves a malfunction of a product that does not have the status of a medical device (MD) or in vitro diagnostic medical device (IVD), it is not covered by vigilance. Example: barcode reader or scanner system.

Examples of vigilance, <u>without</u> reporting to ANSM
Most of these events do not require reporting under vigilance (for MDs or for IVDs) to ANSM, as the clinical consequences / erroneous results or risks of clinical consequences / erroneous results are either non-existent or non-serious. In most cases, it will be a regulatory non-compliance issue, not falling under vigilance.

If the event specifically concerns the UDI carrier readable by machine (AIDC), but the human-readable marking is present, reporting to the ANSM is optional: we recommend reporting these events directly to the manufacturer, as with any non-compliance related to the labelling of a device (outside of vigilance scope).

If the event is detectable before the device is used (for example, upon receipt of a stock of devices) and has not resulted in clinical consequences / erroneous results or does not present a risk of clinical consequences / erroneous results, reporting to ANSM is optional: we recommend reporting these events directly to the manufacturer.

Examples of vigilance, <u>with</u> reporting to ANSM
If the event concerns IVDs specifically used by a medical laboratory automation system and has resulted in an erroneous result, the user must report the incident to the ANSM, as the risk of clinical consequences is considered potentially serious.

If the event concerns an implantable MD for which batch traceability is required and is done electronically, after the actual implantation of the patient, the user must report the incident to the ANSM, as the risk of clinical consequences is considered potentially serious (risk of traceability failure after implantation).