



Unique device identification (UDI)



Background to changes

On 24 September 2013, the US FDA published the [Unique Device Identification \(UDI\) System Regulation](#). In concert with the development of the US rule, the Global Harmonization Task Force (GHTF) and then the International Medical Device Regulators Forum (IMDRF) formed working groups – both chaired by the European Commission – that developed and published global guidance on a Unique Device Identification System¹. The document ‘...provides a framework for those regulatory authorities that intend to develop their UDI systems that achieves a globally harmonized approach to the UDI.’ That is, if regulators follow the principles outlined in these documents, we would achieve a globally harmonized approach to UDI.

On 5 May 2017, the EU Medical Devices Regulation (MDR) (Regulation (EU) 2017/745) and In Vitro Medical Device Regulation (IVDR) (Regulation (EU) 2017/746) were published in the Official Journal of the European Union. The MDR applies from 26 May 2021; the IVDR from 26 May 2022. Among the many changes that the MDR and IVDR bring to the way that medical devices will be regulated in the EU is the introduction of UDI system requirements for almost all medical devices and IVDs (and even some products that have not previously been regulated as medical devices – see, e.g., MDR Annex XVI). And though the MDR/IVDR UDI system requirements are drawn heavily from the IMDRF UDI guidance document – there are some significant implementation differences. Nevertheless, as the specific UDI requirements are spread throughout the regulations, the IMDRF guidance document is an excellent primer for understanding how and why the UDI system is intended to work and how the various pieces fit together – and is worth reading and understanding as part of your UDI implementation.

¹ See https://ec.europa.eu/health/md_sector/new_regulations/guidance_en



Actions

- ① Read and understand the [IMDRF UDI system guidance and MDR/IVDR UDI requirements](#).
- ② Understand your roles and responsibilities with respect to UDI.
- ③ Develop an accurate stock keeping units (SKUs) list of all devices *and accessories*, and their packages subject to the MDR/IVDR.
- ④ Determine the classification of each of these devices and accessories – this will dictate when the label and packages will need to be UDI compliant.
- ⑤ Determine which devices are reused and reprocessed, and therefore subject to the additional direct mark requirement.
- ⑥ Determine where the device master data are located and who owns that data. (Note: it is probably not in a single location/system, but rather spread out across multiple systems and owners; much of it may not even be in a system, but rather on a label or in a spreadsheet.)
- ⑦ Determine and document the roles (e.g. manufacturer, authorized representative, importers, distributor, assembler of systems and procedure packs) and the applicable UDI responsibilities.
- ⑧ Review current labels and packages to determine where and how UDI will be applied.
- ⑨ Develop appropriate barcode implementation strategies, including barcode verification.
- ⑩ Select an issuing agency.
- ⑪ Review current SOPs and systems for inclusion of UDI.
- ⑫ Develop a UDI program and project plan.

Get in Touch

Smart Support is designed to outline the impact of the new regulatory changes, in order for your business to prepare to navigate the transition and implement the new requirements.

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- ✓ Detailed practical guidance on what has changed and what this means for your organization
- ✓ Actions to take now and a summary of what is still to change

To access the full text of the MDR/IVDR Smart Support and find out more about Compliance Navigator, contact us today.

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