Technical Update
European Union Medical Device Regulation and In Vitro Diagnostic Medical Device Regulation

7th African Medicines Regulator's Conference

AMDF Technical Committee Meeting

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EU Directive → EU Regulation

EU Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices (1990s)

EU Regulation on medical devices (2017)

EU Directive 98/79/EC on in vitro diagnostic medical devices (1990s)

EU Regulation on in vitro diagnostic medical devices (2017)

Main Improvements-1

- Stricter pre-market assessment of high-risk devices with the involvement of a pool of experts at EU level.
- Reinforcement of the criteria for designation and of the oversight of notified bodies in charge of certifying medical devices.
- Introduction of a new risk classification system for in-vitro diagnostic medical devices based on international guidance.

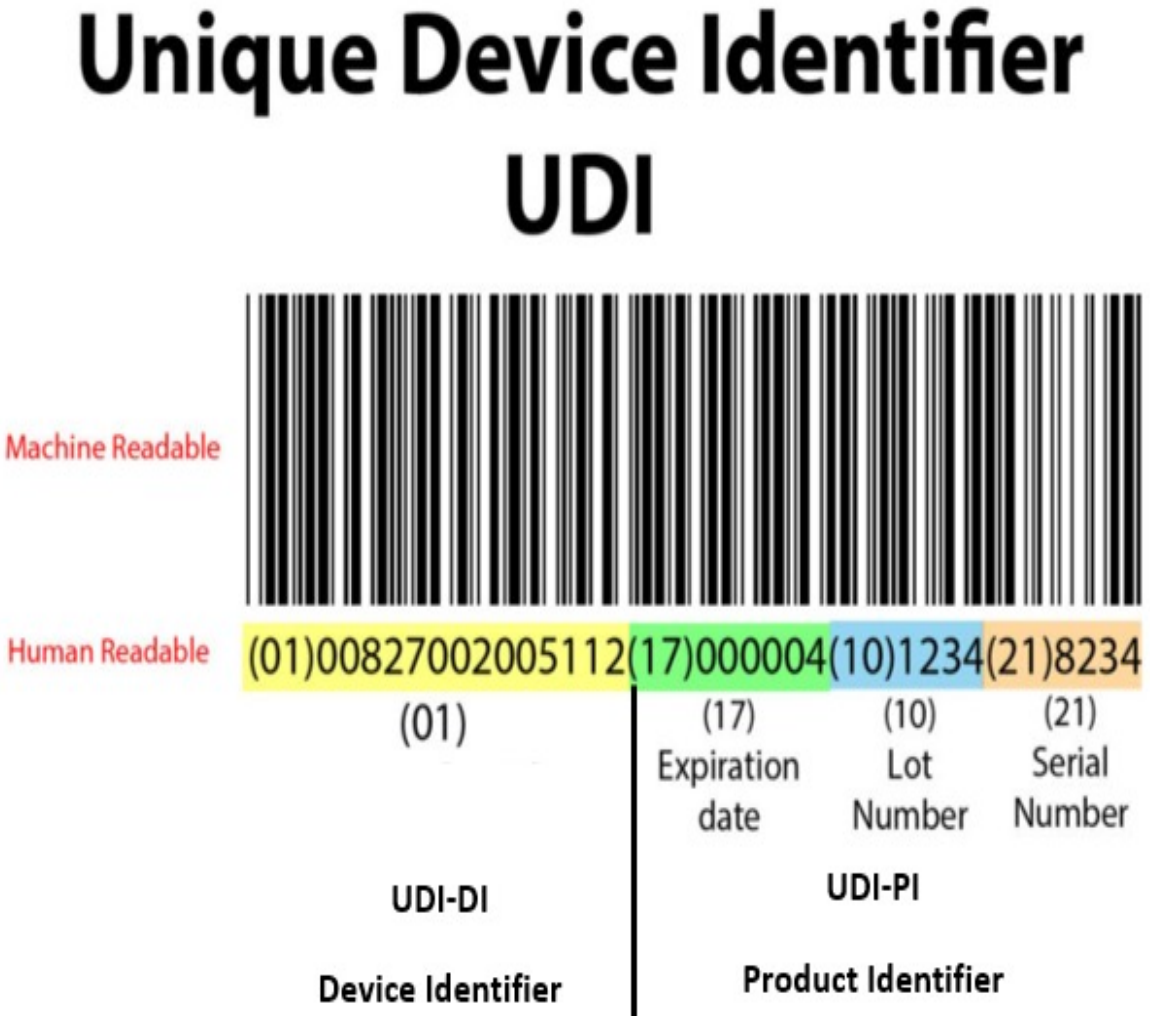
Main Improvements-2

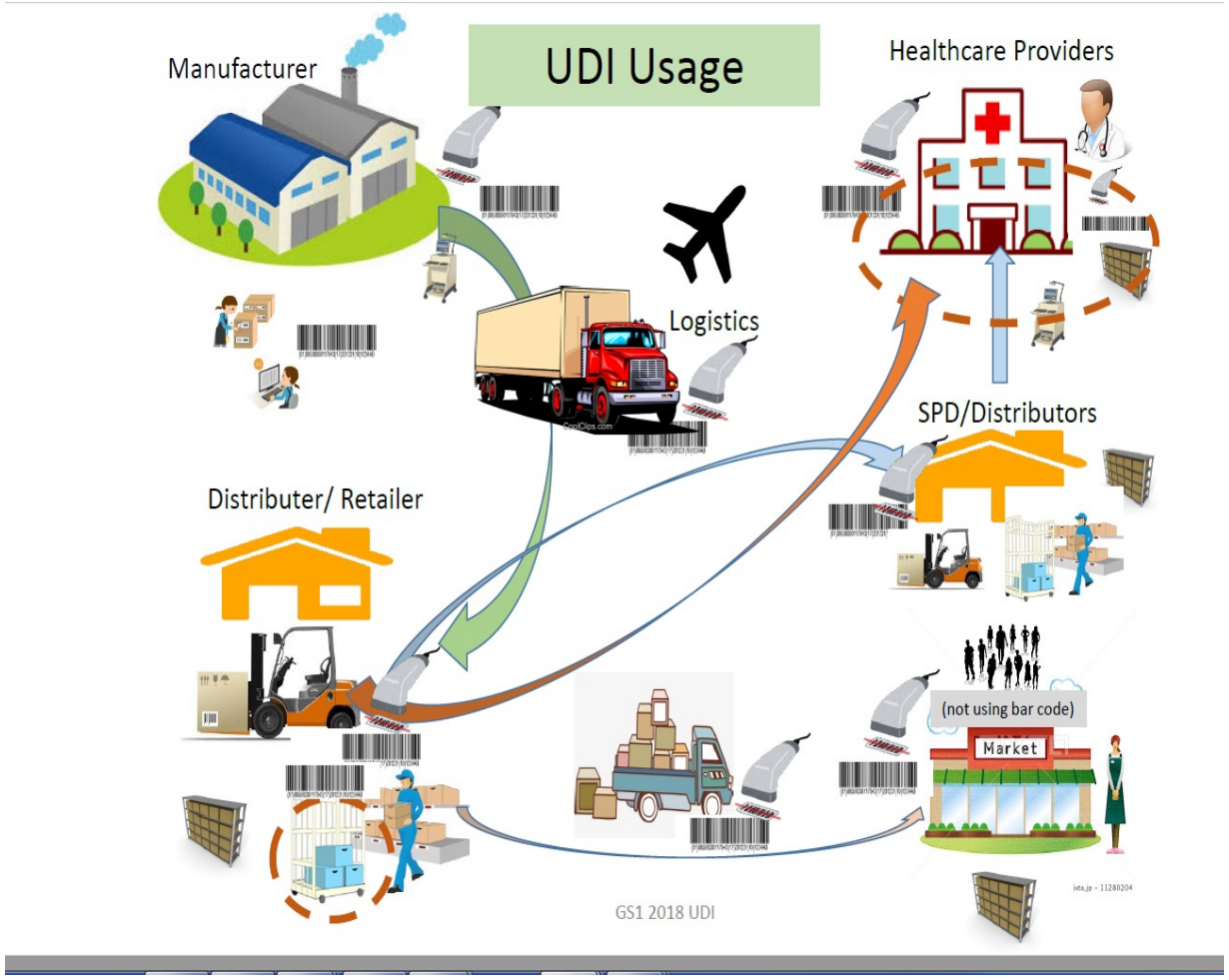
- Reinforcement of the rules on clinical investigation,
- Improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system allowing to trace the device from its manufacturer through the supply chain to the final user.
- Improved coordination between Member States in the fields of vigilance and market surveillance.
- Role and responsibilities of economic operators. Certain new obligations for authorised representatives.

Main Improvements-3

- **Four out of five** *in vitro* diagnostic medical devices are checked by a Notified Body before they are placed on the market
- Manufacturers will need to **generate and provide more in-depth clinical data** to prove safety and performance claims including tighter equivalency standards.
- Manufacturer's obligations in relation to operating effective post-market surveillance of their medical devices are more prescriptive including the need to continuously update risk analysis and clinical documents.
- Reporting obligations for high risk devices including the compilation of Periodic Safety Update Reports (PSURs).
- **Unique Device Identification (UDI) will be implemented** to help track devices throughout the economic operator supply chain and will be required on all labels.

UDI

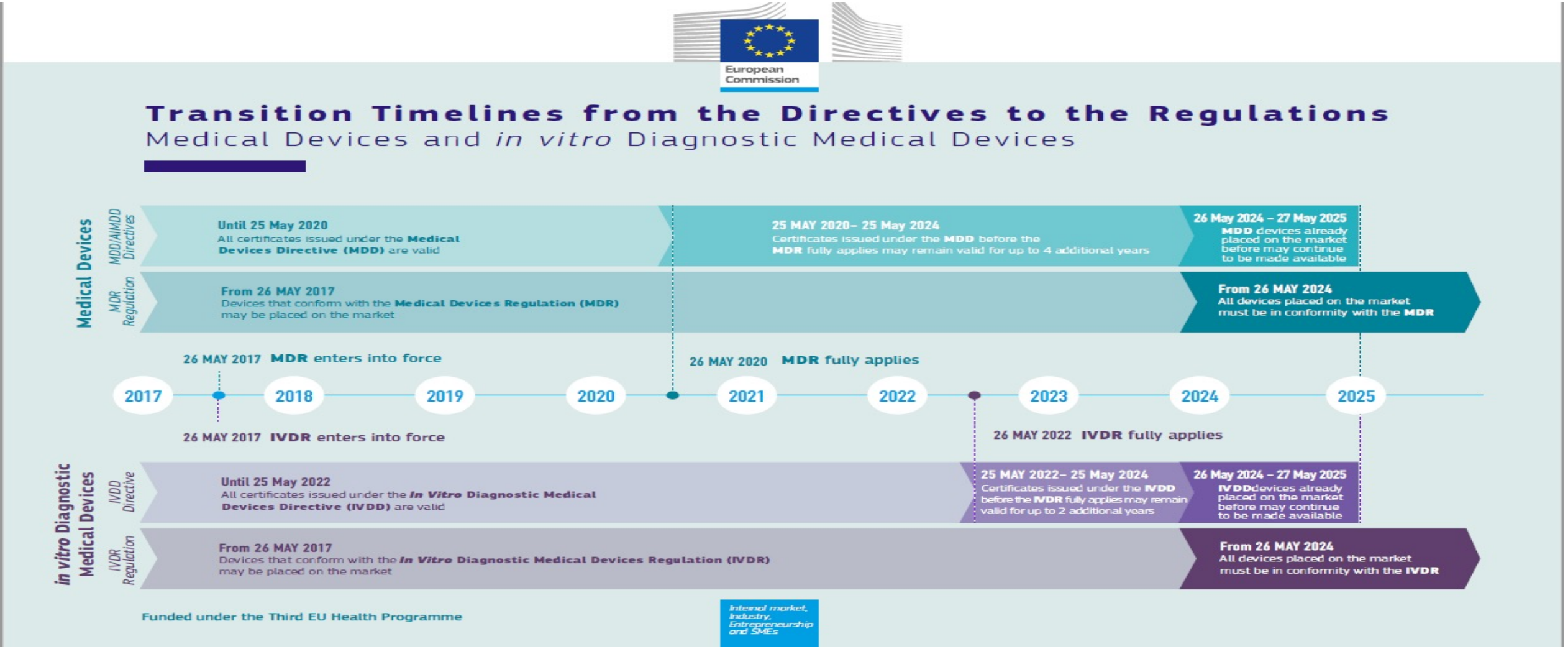

Unique Device Identifier
UDI
Machine Readable
Human Readable
(01)00827002005112(17)000004(10)1234(21)8234
(01)
(17) Expiration date
(10) Lot Number
(21) Serial Number
UDI-DI
UDI-PI
Device Identifier
Product Identifier


UDI Usage
Manufacturer
Healthcare Providers
Logistics
SPD/Distributors
Distributer/ Retailer
(not using bar code)
Market
GS1 2018 UDI

Main Improvements-4

- At least one person in the organization be formally assigned responsibility for ensuring the regulatory compliance of the enterprise
- The extension of the scope of the medical device regulations to products without an intended medical purpose but which are analogous to devices with a medical purpose.
  - Products typically intended for cosmetic purposes.
  - Colored non-corrective contact lenses.

Proposed transition period



Impact of new the EU MD regulations

- **Heightened device safety and effectiveness** and will support transparency throughout the medical device market
- Utilization of a Unique Device Identifier (UDI) system publicly available and easily accessible will be critical to supporting physician and patient attitudes toward various medical devices
- The overall number of Notified Bodies is expected to decline leading to bottlenecks and commercialization delays
- Manufacturers: increased costs, commercialization delays, and device removals
- Smaller companies will likely be pushed out of the market
  - Unable to comply with the MDR by the date of application,
  - Lack of resources, time constraints, or both.
  - Companies will likely have to make difficult strategic decisions to prioritize certain products (generate sufficient sales to cover the costs of compliance)

Regulators Considerations

- Prepare contingency plans in case of
  - Reduced or delayed supply
  - Withdrawal of products
  - Critical products/all similar products
  - Products replaced
  - Inferior goods
  - IVD mark removed may lead may change to Research Use Only (RUO) status
  - ? What is going to happen the rest of the world version products (Non-CE Marked products)