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Publication of Regulations on Medical and In Vitro Diagnostic Devices

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To conform Turkish regulations extant on medical and in vitro devices to those of the EU, and to protect and preserve the wellbeing of Turkish consumers, the Turkish Pharmaceuticals and Medical Devices Agency (the "**Agency**") published, in Official Gazette numbered 31499, the Regulation on Medical Devices ("**Medical Device Regulation**"), and the Regulation on In Vitro Diagnostic Devices (the "**IV Device Regulation,"** and together with the Medical Device Regulation, collectively, the "**Device Regulations**"). The Device Regulations repeal and supersede prior applicable regulations.

Regulations aim to protect the health and the safety of the patients, users, and third parties, providing high-quality medical devices to the market, supporting the improvements regarding the medical devices, creating a clear and sustainable market in Turkey, and ensuring compliance with EU Regulations.

Most notably, Device Regulations

- Secure the personal data obtained during the clinical trials,
- Broaden and update the range of products regulated as medical devices, such as devices that were not defined as "medical device" before yet includes similar risks,
- Tighten CE mark regulations for medical devices,
- Change the classification of some devices, leading them to be subject to CE requirements,
- Hold manufacturers liable for ensuring the safety of their products, and requires maintenance of safety testing records, including a system for clinical evaluation and surveillance,
- Require importers to present complete CE mark documentation in Turkish or in any of official EU languages.
- Require manufacturers to provide device samples or inspection access to the Agency- requires an UDI (unique device identification) code to all devices for tracking the devices easily,
- Require economic operators, manufacturers, authorized representatives and importers to register in the EUDAMED ("European Databank On Medical Devices") database, which is scheduled to be officially launched on May 26, 2022,
- Until EUDAMED becomes fully functional, the relevant provisions of the prior regulations regarding vigilance reporting, clinical investigations, registration of devices and of economic operators and certificate notifications shall continue to apply.
- With respect to IV Device Regulation specifically, it requires manufacturers to present adequate clinical data demonstrating compliance with applicable safety and performance requirements.
- Regulations regarding the notifications and the documents to be uploaded to the electronic system will enter into force 6 months after the Commission publishes a notification in the Official Journal of the EU that EUDAMED is fully functional and meets its functional specifications.
- Implantable and devices cited as class III that incorporating UDI carriers will take effect on the date of publication, effective 26 May 2021, 26 May 2023 for class IIa and IIb devices and 26 May 2025 for class I devices. Implantable and class III devices for self-contained reusable devices will enter into force on 26 May 2023, for class IIa and IIb devices on 26 May 2025, and for class I devices on 26 May 2027.
- The coordinated evaluation procedure for clinical trials will take effect on 26 May 2027 and other provisions is take effect as of 26 May 2021.
- In accordance with the In Vitro Diagnostic Medical Device Regulation, the regulation on the coordinated evaluation procedure for Performance studies will enter into force on 26 May 2029, and other provisions on 26 May 2022, one year after the Medical Device Regulation.

The full text of the Medical Device Regulation is available at this link and IV Device Regulation at this link. (Only available in Turkish)

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