

***in vitro* Diyagnostik Tıbbi Cihazlarla İlgili Yararlanılan Düzenlemeler**

Yasal mevzuat

1. **Avrupa Parlamentosu ve Konseyi.** Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR). *Official Journal of the European Union*. 2017;L117:176–332.
2. **T.C. Sağlık Bakanlığı, Türkiye İlaç ve Tıbbi Cihaz Kurumu (TİTCK).** İn Vitro Tanı Amaçlı Tıbbi Cihaz Yönetmeliği (2017/746/AB ile uyumlu). Resmî Gazete, 2 Haziran 2021, Sayı: 31499.
3. **Türkiye İlaç ve Tıbbi Cihaz Kurumu (TİTCK).** Ürün Takip Sistemi (ÜTS). <https://utsuygulama.saglik.gov.tr/UTS/>

Uluslararası Standartlar ve Terminolojiler

1. **European Commission.** European Medical Device Nomenclature (EMDN). <https://webgate.ec.europa.eu/dyna2/emdn>
2. **European Commission.** Medical Devices – EUDAMED. https://health.ec.europa.eu/medical-devices-eudamed_en
3. **GS1.** Healthcare Unique Device Identification (UDI). <https://www.gs1.org/industries/healthcare/udi>
4. **HL7 International.** FHIR® Release 5 (Fast Healthcare Interoperability Resources). <https://hl7.org/fhir>
5. **Logical Observation Identifiers Names and Codes (LOINC®).** Regenstrief Institute. <https://loinc.org>
6. **Medical Device Coordination Group (MDCG).** Guidance documents on Regulation (EU) 2017/746 (IVDR). European Commission. https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
7. **SNOMED International.** SNOMED CT. <https://www.snomed.org>
8. **The Unified Code for Units of Measure (UCUM).** <https://ucum.org>