

Amendments on the Regulation on Testing, Control and Calibration of the Medical Devices

14 Oct 2021

Medical Devices Regulation Amending the Regulation on Testing, Control and Calibration of the Medical Devices ("**Amendment Regulation**") has been published in Official Gazette dated 10 September 2021 and numbered 31594.

Amendment Regulation issued by the Turkish Pharmaceuticals and Medical Devices Agency ("**Agency**") regulates the following issues:

- Legal grounds of the regulation have been amended as (i) the Law on the Product Safety and Technical Legislation dated 5 March 2020 and numbered 7223 and (ii) relevant provisions of the Presidential Decree numbered 4 on Organization of Affiliated, Related, Associated Institutions and Organizations with Ministries and Other Institutions and Organizations published on the Official Gazette number 30479 dated 15 July 2018.
- The application file to be submitted to the Agency by the conformity assessment institutions to obtain authorization documents required for performing testing, control and calibration services shall include the registry certificate.

The full text of the Amendment Regulation published in Official Gazette dated 10 September 2021 and numbered 31594 is available at this [link](#) (Only available in Turkish).

Related Practices

- [Product Liability and Consumer Protection](#)

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