The Guideline on the Implementation of the Regulation on Test, Control, and Calibration of Medical Devices was Published

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On 6 January 2022, the Turkish Medicines and Medical Devices Agency ("**Agency**") published the new Guideline ("**Guideline**") on the Implementation of the Regulation on Test, Control, and Calibration of Medical Devices ("**Regulation**").

With the Guideline, the previous guideline on the implementation of the Regulation was abolished.

The Guideline clarifies the procedure and principles under the Regulation and consists of four sections. The application process and the process regarding the test, control, and calibration of the Conformity Assessment Organizations ("**CAO**") are detailed in the Guideline.

Main points clarified with the Guideline are as follows:

- Organizations can file applications through an online platform named ÜTS. The Guideline explains all the steps for the application as well as the required documents for the application process.
- After filing the application, as a next step the Agency examines the applications and if it sees a defect in the application, it may request the Organizations to correct these deficiencies via ÜTS within forty-five days. The Agency will issue the authorization certificate if it gives approval as a result of the on-site examination carried out in the organizations that apply. Moreover, they will be able to issue working certificates for the responsible managers and experts, employed by a CAO.
- The Organizations will also be able to carry out the process related to the test, control, and calibration of the medical devices within the scope of the authorization certificate through ÜTS. They are obliged to issue a report after the finalization of the test, control, and calibration process for the devices within the scope of the authorization certificate. It is a must to have a distinctive sign including the authorization certificate of the Organization in the reports.
- Organizations are obliged to carry out the calibration proceedings at least once a year to ensure whether the reference devices they use comply with national or international measurement standards. This is not sought for organizations with accreditation certificates.
- The working and authorization certificates that were issued within the scope of the Regulation and before the effective date of the Guideline will continue to be valid on the condition that they are in accordance with the provisions of the Guideline.

Please see this link for the full text of the Guideline (Only available in Turkish).

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