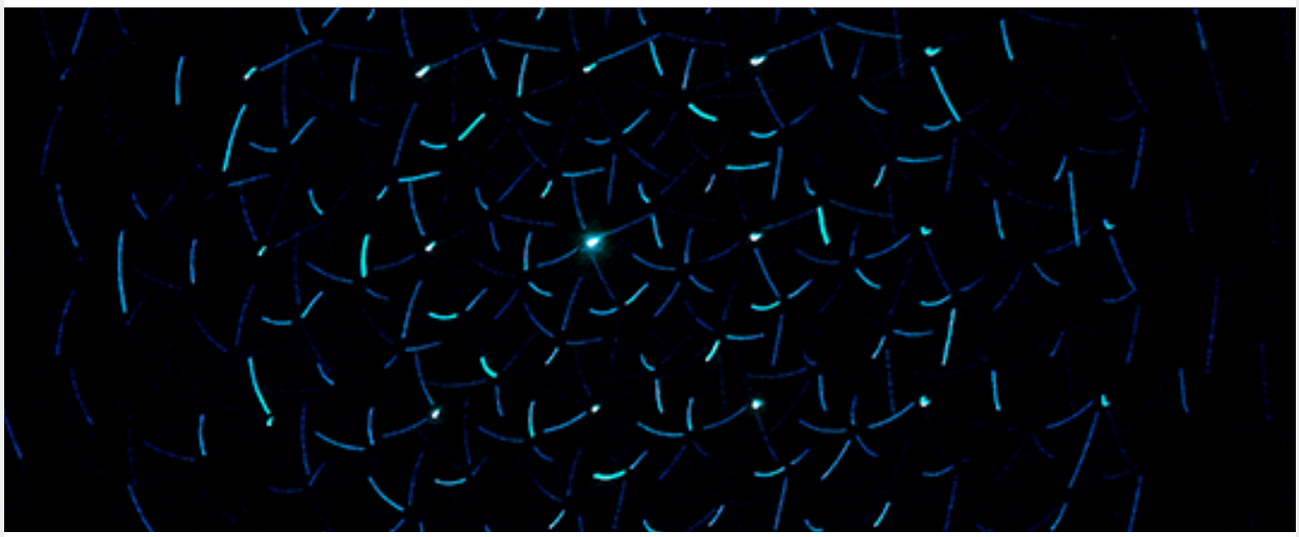
Developments in Medical Device Legislation

March 2024



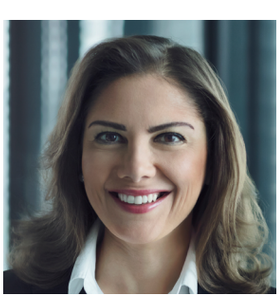
Dear Clients, Colleagues and Friends,

Following the entry into force of the Communiqué on the Determination of Common Specifications for Product Groups Without an Intended Medical Purpose Listed in Annex XVI of the Medical Device Regulation ("**Communiqué**") published in the Official Gazette dated 14 March 2024, the Guideline on Determination of Common Specifications for Product Groups Without an Intended Medical Purpose Listed in Annex XVI of the Medical Device Regulation has been repealed with the approval of the Turkish Medicines and Medical Devices Agency.

With the Communiqué, the scope of the harmonisation clause with the European Union ("**EU**") legislation has been extended, and the timelines have been extended to align with the revised transitional provisions for product groups without an intended medical purpose, such as contact lenses, liposuction and laser equipments, as outlined in EU legislation. The regulations introduced by the Communiqué are not only significant in terms of the compliance of sector players with the legislation, but also hold significant importance in harmonising with the EU legislation.

Please do not hesitate to contact us for any further information on this briefing.

King regards,



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