Announcement on new medical device requirements

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The EU Medical Devices Regulations (*(EU) 2017/745*) (MDR) will become applicable on 26 May 2020. As a non-EU country, the Turkish Medicines and Medical Devices Agency published an *announcement* (Turkish language) on 30 December 2019 advising that harmonisation of Turkish regulations with the new rules is to continue.

The announcement notes that the MDR sets new principles for manufacturers, importers and distributors, and new requirements have been defined in terms of classification, conformity assessment routes, clinical assessment and individual device monitoring. Particular attention is drawn to the fact that some devices previously classified as Class I medical devices will now require notified body assessment.

The agency concluded that it is important for manufacturers and importers to evaluate whether their devices need to be reclassified according to the MDR to adapt to the new requirements and start conformance immediately.