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QUOTED. 11 June 2019. Bassil Akra.

by

TÜV SÜD Product Service's Bassil Akra is concerned that there won't be enough notified bodies to audit to the new EU Medical Device and In Vitro Diagnostic Regulations when they come into force in 2020 and 2022, respectively. Check out his comments here.

"We are hiring like crazy. As a notified body, we have been hiring for the MDR and IVDR for the past three, four years. But it will not be sufficient because we can't find all of these experts. They are not available out there. The market is getting really tough. And this is the point where we expect for IVD to be a big problem because there will not be enough notified bodies. And this is where I believe that IVD is going to be the biggest big bomb that we will see in the next two years." – Bassil Akra, VP, TÜV SÜD Product Service

- Find out more: *Notified Body Q&A: 3 NBs Talk EU MDR Enforcement, The IVDR 'Big Bomb,' 'Tough' Regulators – And More Insights*