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Top ten tasks to prepare for the UK Conformity Assessment

November 2020 – As the medical device industry gears up to implement a new set of requirements following Brexit, Maetrics has released a concise guide summarizing the known requirements so far and priority areas where manufacturers can give their immediate attention.

As manufacturers work hard towards compliance with the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), it is important not to overlook another pending challenge: businesses with products on the UK market will need to comply with the requirements of the UK's new regulatory regime. The delay of the EU MDR date of implementation to May 2021 means that manufacturers have time to start planning. Moreover, EU MDR and IVDR compliance activities are likely to place them in good stead for the emerging post-Brexit system.

One of the first action points for affected organizations will be to monitor developments and assess the level of overlap between the EU and UK regulatory regimes to prevent unnecessary duplication of efforts. As more information becomes available, Maetrics' new guide provides a list of ten actions that manufacturers can build into their regulatory planning, and clearly breaks down what we already know about the UK Conformity Assessment certification (UKCA mark).

Steve Cottrell, President at Maetrics, comments: "Our industry is facing a number of ongoing regulatory pressures, and this makes strategic planning more critical than ever. Maetrics' aim with this mini-guide is to provide an easily absorbed overview that will help with preparations for the UK's upcoming certification. Businesses should immediately begin to identify where more information is still needed, as well as potential areas of complexity. These information gaps can then be filled in and addressed efficiently as and when there are new developments."

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About Maetrics
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