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New CE Mark Requirements for Clinical Data Evaluation – Are you in compliance?

Medical device marketing and regulatory professionals, are you aware of the revisions to the European Union Medical Device Directive (“EU MDD”) that took effect March 21, 2010? Are you in compliance?

As you know, all medical devices bearing the CE mark must comply with the essential requirements established in Annex I of the MDD, ensuring, among other things, that they do not compromise the health and safety of patients, users and any other person and that they perform as intended by the manufacturer.

NEW REQUIREMENT: As of 21 March 2010 the EU MDD requires that “clinical data” be provided for ALL medical devices.

This may be a literature review or clinical investigation depending on device class and use. **Failure to conform to the new requirements may result in major non-conformance at your next Notified Body audit.**

HOW TO COMPLY: Evaluation of clinical data must follow a defined and methodologically sound procedure based on:

1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:
 - a. there is demonstration of equivalence of the device to the device to which the data relates, and
 - b. the data adequately demonstrate compliance with the relevant essential requirements.
2. Or a critical evaluation of the results of all clinical investigations made.
3. Or a critical evaluation of the combined clinical data provided in a. and b. above.

Source: MDEG – 2009–12-01 MSOG Class I Guidance
Rev. 1_2009-06 Compliance and Enforcement group (Ref MDD Annex X)

Are you in compliance with these new requirements?

If you are too busy or do not have internal resources to conduct these evaluations, MedIntelliBase can help. We perform quick, thorough literature reviews - MedIntelliBase Custom LitReviews® - using our comprehensive database of scientific, clinical, and technical publications to provide comprehensive reports supporting your medical devices. This is a comprehensive view of the literature route consisting of verified findings with objective evaluations by medical literature and regulatory experts. You will receive a fully documented and referenced point-in-time literature review that is a fully referenced & qualified analysis. The review can be used to establish substantial equivalence to predicate devices.

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