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ABSTRACT

HOW DOES THE NEW MEDICAL DEVICE REGULATION OF 2017 EFFECT THE DEVICE MANUFACTURERS AND THE MARKET?

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Medical Devices are products used by the Medical industry to supplement their practice and for purposes such as diagnosis, measurements, implants etc. Thus, Medical Devices play a very prominent role in the Medical industry. It is thus very important to regulate the quality and safety standards of such devices as they are used for medical purposes and are in close contact with numerous individuals. This Article talks about the two New Regulation on "Medical Devices" and on "In-Vitro Diagnostic Medical Devices" released by the EU in 2017 repealing the three earlier existing Directives. The Article focus on the amendments brought into with the implementation of the New Regulations of 2017 and strikes a comparison between the repealed Directives. In the process the article highlights the CE marking process which is a mandatory provision to be complied with before the release of the Medical Device in the market. This Article is a comparative study and follows the Impact Analysis methodology to reach its conclusion.

- Key Words: Medical Devices Directives, Regulation (EU) 2017/745 and 2017/746, CE marking process, Notifying Body.