EU to release NEW Medical Device Regulations!

In June 2016, the European Parliament released the consolidated texts of the **new EU Regulation Proposals on Medical Devices** and **In-Vitro Diagnostics Devices**. The texts, published on the European Parliament website, reflect the position agreed by the **European Parliament** and the **Council of the European Union**. Once in force, they will become Regulations (not Directives, as they have been so far), which means they will be legally binding throughout the European Economic Area (EEA) market without being transposed into **national laws**. The proposals present **new provisions** which will surely impact the CE Marking as well as the EU compliance for manufacturers of medical devices and in-vitro diagnostics.

Future Expectations & Application

The regulations include **many new provisions** which will have an impact on the EU compliance and CE marking process for medical devices currently on the market or soon to be introduced. As the published proposals are most likely the **final texts** and taking into consideration that the **implementation of the new provisions** will take time, it is highly advisable for manufacturers to implement as soon as possible **the new requirements** applicable to their medical devices in order to **safeguard their EU compliance.**

Texts available on Obelis website

The consolidated texts of the **new EU Regulations on Medical Devices** and **In-Vitro Diagnostics Devices** are now available **on Obelis website – on our** Legislation page.

If you are interested to find out more about the **new provisions**, feel free to consult the new regulations on our website or contact us for more information.