The European Union Regulation N. 745/2017: Opportunities and Challenges

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Abstract

Theoretical Background The next 26 May 2021 will enter into force the European Regulation on medical devices, procrastinated of one year cause Covid.

Aims to explore the increased level of attention not only on the safety of the devices, but also on their effectiveness, placing in the hands of the producers important responsibilities of control over the production and marketing of the device

Methods: Through a timely analysis of the content of the Regulation highlight the innovations required. There are two main areas to implement, 1) increased the essential safety requirements to which are added usability and clinical effectiveness 2) the marketing, with the aftermarket of the device. Art. 5 of the Regulation is dedicated to hospitals and all health facilities that realize in their own medical device.

Findings and implications Since 2007, corrective measures have been introduced to the Regulation: the main one has impacted medical software, for which major changes are expected. Whereas in the previous Directive 93/42/EEC software covered the concept of medical devices. In addition, medical software manufactured in accordance with the classification rules of the EC Directive are for the most part in Class I, therefore without the need of the notified body, while with the new European Regulation these software will pass for a good part in classes II A and II B, for which it is necessary the control of the notified body.

Keywords: List four to seven keywords separated with commas