Advisera Expert Solution released the full text of the EU Medical Device Regulation

ZAGREB, CROATIA, June 30, 2020 /EINPresswire.com/ -- Advisera Expert Solutions Ltd, the market leader in providing documentation and helping organizations implement top standards and frameworks, released a full text of the Medical Device Regulation. The MDR is postponed due to the COVID – 19 pandemic and will be applicable on May 2021 in all EU member states.

This Regulation arranged by chapters, sections, and articles, published on the 13485Academy website, applies to all companies that manufacture, import, or distributes medical devices within those EU states. Medical Device Regulation lays down rules concerning the placing and making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. MDR also applies to clinical investigations concerning such medical devices and accessories conducted in the European Union.

Chapter 2 is dedicated to a market and rules how companies should, from 2021, put into service of devices, but also obligations of economic operators, reprocessing, CE marking, and free movement.

If you are a company which produces medical equipment in Article 5, Chapter 2, you will find all examples when you can place your device in the market, like the first rule says that the medical device can be placed in the market only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose. In this chapter, it is written in detail about the general obligations of manufacturers, importers, distributors, and for each of these subjects are provided specific requirements.

Regulation is saying the manufacturers should have available at least one person, within their organization, which will be responsible for regulatory compliance. This person needs to possess the requisite expertise in the field of medical devices, like a diploma, certificate, or other evidence of formal qualification.

The most important rules that chapter 3 is covering is about identification and traceability of devices, registration of devices and economic operators, but also a summary of safety and clinical performance, European database on medical devices.

Manufacturers need to provide a summary of safety and clinical performance says in Article 32, chapter 3, and by MDR this summary should include the identification and purpose of the

device, description, possible diagnostic or therapeutic alternative, the summary of clinical evaluation, information on any residual risks and any undesirable effects, warnings, and precautions.

The whole chapter 4 is referring to notified bodies, authorities responsible for notified bodies, what will be their tasks, who is responsible for them, and monitoring their activities.

Chapter 5 brings the classification of all devices, and it is written that they need to be divided into classes I, IIa, IIb, and III. When it comes to the clinical evaluation, the manufacturer is the one who needs to specify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. In this chapter, you will find separate articles about the clinical investigation on the incapacitated subjects, minors, pregnant or breastfeeding women, in emergencies, but also an application for clinical investigation, requirements regarding other clinical investigations, etc.

This is not all, as a manufacturer, you will need to plan, establish, document, implement, maintain and update a post-market surveillance system, for each device you are producing, and in Article 83 you will find detailed information about data that needs to be gathered for this surveillance system. If we are talking about vigilance, all manufactures should report to the relevant authorities if there was any serious incident involving devices made available on the European Union market.

It is also important to read what brings chapter 8, regarding cooperation between member states, medical device coordination group, expert laboratories, expert panels, and device registers. Personal data and commercially information need to be protected by all parties involved in the application of MDR.

In the end, in Annexes, it is pointed out what is the general requirements of the device, regarding design and manufacture, but also what technical documentation is required, that should be presented in a clear, organized, searchable, and unambiguous manner and include in particular the elements listed in this Annex.
If you would like to read the full text of MDR, you can do that – HERE!

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