Advisera released a new white paper on EU MDR mandatory documents and records

ZAGREB, CROATIA, March 20, 2020 /EINPresswire.com/ -- March 19, 2020 – Advisera Expert Solutions Ltd, the market leader in providing documentation and helping organizations implement top standards and frameworks, released a new white paper titled "EU MDR Checklist of Mandatory Documents", with detail lists of all the mandatory documentation needed by the new European Union Medical Device Regulation (EU MDR).

The white paper, available for free download on the 13485Academy website, one of the Academies of Advisera, is intended for all companies or organizations who are planning to sell or distribute medical devices in the European Union and want to know exactly what this regulation requires.

The European Union Medical Device Regulation (EU MDR) was released in May 2017. by the European Parliament and the Council. This new regulation intends to ensure a higher standard of quality and safety for medical devices that are produced or supplied into member countries of the EU and to provide the best protection for the health of patients.

The transition period from the previous directive European Union Medical Device Directive (MDD) to EU MDR regulations lasts for three years and as the 26th of May implementation deadline approaches, some companies and organizations still need guidance through EU MDR regulation and detail information about the mandatory documentation.

That was the main reason why Advisera Expert Solutions Ltd experts did detail research and in this free white paper gathered all the necessary information, so you don't have to deal with anything besides collecting mandatory documentation in one place. After you have everything in place, you as a company or organization can apply for a CE mark certification (it indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area).

Key insights from the white paper "EU MDR Checklist of Mandatory Documents":

In the section General requirements, you will find information about the EU Declaration of Conformity document, but also a list of all the aspects that medical device manufacturers need to include in a Quality Management System (QMS). Besides that, there is also an important section in this regulation which includes a list of all device identification (UDI) system for medical devices.

Risk management also needs to be done for each medical device and appropriately documented, because this will demonstrate your abilities to assess and control the risks that are posed by your medical device throughout the life cycle of the product. When you download the white paper, in the section about risk management, you will find what includes the general process for risk assessment.

As EU MDR regulation demands, you will also need to provide clinical evaluation of your medical devices, that will demonstrate their safety and effectiveness. You will need to make the Clinical Evaluation Plan, and in the white paper you will find what information needs you will need to collect, but also what precise data your post-market surveillance plan needs to include.

In the end, your company or organization, in order to ensure compliance of the medical devices with the MDR, will need to create technical files and in “EU MDR Checklist of Mandatory Documents” you will find what the technical file documentation includes.

About Advisera Expert Solutions Ltd:
Advisera was founded in 2009. and has quickly become a market leader in providing documentation and online support for EU GDPR, ISO 27001, ISO 22301, ISO 9001, ISO 14001, ISO 45001, AS9100, ISO 13485, EU MDR, IATF 16949, ISO 17025, ISO 20000 and ITIL. Advisera offers specialized guidance, tools, trainings, books, professional expertise, and complete documentation, so the people with no prior knowledge can implement those frameworks into their companies. At the moment their products are in 13 languages, they have customers in more than 100 countries worldwide, and more than 100,000 registered users on their website.

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