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Digital Health Compliance
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salesforce health cloud

Medical Device Regulation

You are without a doubt aware that the Medical Device Regulation has been published and therefore enacted. After the transition period ends, all medical software must comply with the necessary requirements. Do you know if your Salesforce Health Cloud platform, portals, medical applications and other software classify as a medical device? What do you need to do if your digital solutions need to have a CE approval? What will the impact be on your organization, processes and partners? It is important to interpret the Regulation correctly so that the controls are aligned with the goals of the organization.

When is software, such as an application or a portal, a medical device?

Software has been given a specific place within the Medical Device Regulation. Software intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

1. Investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life.
2. Providing information by means of in vitro examination of specimens derived from the human body.
3. In case of disease: diagnosis, prevention, monitoring, treatment or alleviation.
4. In case of injury: diagnosis, monitoring, treatment alleviation or compensation.

Examples

The examples presented in this onepager are illustrative. This in particular concerns the expectations and goals within the applications in combination with the risk for a user / patient. The reference framework under the Medical Device Regulation (hereinafter: the Regulation) are limited for the time being.

Class I Low risk	Class IIa Low/medium risk	Class IIb Medium/high risk	Class III High risk
An application that informs patients about the prevention of sport injuries.	A platform such as decision support in a treatment plan of someone with a minor injury, for example, a sprained ankle.	An application for patients that based on a pain score makes decisions about the treatment plan to be followed for the patient.	A platform equipped with artificial intelligence (AI) decision support in life-threatening situations.

Note: in all examples it depends on the specific situation. Circumstances may change the qualification and in particular classification of a medical device. After all, the potential risks depend on various factors.

When classifying software as a medical device, the risk and purpose of the medical device is considered in particular. Both variables are decisive for the underlying risk class.

Class I medical devices are a low risk. This includes software that does not provide decision support for diagnostic or therapeutic purposes.

Class IIa medical devices involve a low-level risk. This includes software that provides information for decision support of the diagnosis or therapeutic purposes and software that monitors physiological processes.

Class IIb medical devices are at medium risk. Again, it concerns software intended to provide information that is used to make decisions for diagnostic or therapeutic purposes. These decisions, however, can directly or indirectly lead to a serious deterioration of the state of health or a surgical procedure.

Class III medical devices carry a high risk. This includes software that provides information for decision support for diagnostic or therapeutic purposes and can directly or indirectly lead to death or an irreversible deterioration of the health status of the individual user.

Our services:

Statement of applicability

For your Salesforce platforms it is important to understand in which category they fall for regulatory purposes. What is the purpose of the platform? And under which risk class does it fall?

As part of the Deloitte Digital implementation team, we as a compliance partner can make this inventory together with you and draw up a statement of applicability in which the right risk classes are listed.

Roadmap to compliance

What are the things 'to do' in order to comply with the Regulation? And what are the priorities?

As part of the Deloitte Digital implementation team, as a compliance partner we screen your organization, (software development) processes and daily operations and provide you with a roadmap that provides answers to all your questions.

Support

It is of the utmost importance that your employees understand and support the processes and controls that are implemented. Your entire organization needs to follow these standards.

We can help you during implementation but also in the operationalization phase. We enable you to become compliant and make sure you remain compliant as well.

For more information, please visit our website www.digitalhealthcompliance.com

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