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A DRUG PRESCRIPTION ASSISTANCE SOFTWARE CAN BE A MEDICAL DEVICE

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In its judgment dated 7 December 2017 (case C-329/16), the Court of Justice of the European Union (CJEU) considered that software, of which at least one of the functions makes it possible to use patient-specific data for the purposes, inter alia, of detecting contraindications, drug interactions and excessive doses, is, in respect of that function, a medical device within the meaning of the Directive 93/42/EEC concerning medical devices (MDD).

According to the CJEU, software that cross-references patient-specific data with the drugs that the doctor is contemplating prescribing, and is thus able to provide the doctor, in an automated manner, with an analysis intended to detect, in particular, possible contraindications, drug interactions and excessive dosages, is used for the purpose of prevention, monitoring, treatment or alleviation of a disease, and therefore pursues a specifically medical objective, making it a medical device within the meaning of the MDD.

On the contrary, software that, while intended for use in a medical context, has the sole purpose of archiving, collecting and transmitting data, like patient medical data storage software, the function of which is limited to indicating to the doctor providing treatment the name of the generic drug associated with the one he plans to prescribe, or software intended to indicate the contraindications mentioned by the manufacturer of that drug in its instructions for use, does not fall within the scope of the MDD.

The CJEU adds that to assess whether a software is a medical device in the meaning of the MDD, it does not matter whether software acts directly or indirectly on the human body. The essential criterion is that its purpose is specifically one of those set out in the definition of a medical device (such as the diagnosis, prevention, monitoring, treatment or alleviation of disease).

The stakes of the qualification are clear. Any medical device, including software, must compulsorily bear a CE marking of conformity when it is placed on the market. Such marking indicates that the product has been subject to an assessment of its conformity with the requirements of the MDD. As a consequence of such marking, Member States may not create obstacles to the placing of the device on the market. In the case at stake, France imposed an additional national certification obligation on a drug prescription assistance software bearing the CE marking. As a consequence of the CJEU's judgment, such an obligation must be considered as contrary to the MDD.

The CJEU also clarified that if medical software comprises both modules that meet the definition of the term 'medical device' and others that do not meet it and that are not accessories to a medical device, only the former falls within the scope of the MDD and must be marked CE. The manufacturer of such mixed software is required to identify which of the modules constitute medical devices, so that the CE marking can be affixed to those modules only.

There is no doubt that this judgment of the CJEU will remain valid under the future legislation, namely the Regulation 2017/745/EU on medical devices (applicable as from 26 May 2020). This Regulation explicitly states that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device (such as the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease), qualifies as a medical device.

For more information on this future legislation, you can contact us or have a look at our previous news: The new legal framework applicable to medical devices.

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