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Italian national legislation adapted to MDR

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GLORIA GELOSA

Introduction

On 26 May 2021, four years after its adoption in April 2017, the EU Medical Device Regulation (MDR) (2017/745/EU) took effect in the European Union. This regulation replaces the EU Medical Devices Directive (93/42/EEC) and the EU Active Implantable Medical Devices Directive (90/385/EEC).

The MDR concerns the putting into service or commissioning, placing and making available on the EU market of medical devices for human use and related accessories. Article 2(1) of the MDR defines such medical devices as follows:

> *Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more . . . specific medical purposes . . . and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.*

Adaptation of Italian legislation

On 23 April 2021 the European Delegation Law 2021 (Law 53, 22 April 2021) was published in the *Official Journal* and on 8 May 2021 it took effect.

Article 15 of the European Delegation Law 2021 states that within 12 months as of 8 May 2021, the government will adopt one or more legislative decrees to adapt the domestic law to the new framework established by the MDR. In particular, the government must establish the content, timing and manner of all of the records and information that manufacturers and distributors of medical devices in Italy are required by the MDR to communicate to the Ministry of Health. Also, it must reorganise and coordinate the activities between public bodies in charge of the governance of medical devices and establish effective penalties for infringement of the applicable provisions.

The Italian government must also address a crucial aspect relating to medical devices, in particular, to "software as medical devices" (SaMD), ie, the coordination of the new rules introduced by the MDR with those concerning the processing of personal data. By using medical devices that are increasingly digital in nature and connected, both the manufacturers and providers of such products will inevitably collect and process a great volume of personal data relating to the health of individuals. This brings about the issue of safeguarding to the fullest extent possible the right to privacy of patients and users of medical devices. Therefore, the question arises as to whether compliance with the EU General Data Protection Regulation should become one of the elements to be assessed for the device certification purposes.

While some may say that more attention should have been given from the beginning to the key topic of data protection in drafting the MDR, some general principles relating to the protection of personal data are indeed provided thereby – for example:

- all parties subject to MDR must "respect the confidentiality of information and data obtained in carrying out their tasks";
- software must be developed and manufactured in accordance with the state of the art, taking into account information security, verification and validation; and
- devices must be designed and manufactured taking into account cybersecurity, with a view of being protected against unauthorised access.

These provisions will constitute a solid basis for implementing the future Italian legislation concerning data protection in relation to medical devices.

On 25 May 2021 the Ministry of Health further issued a communication that provided the first immediate indications concerning the adaptation of Italian law and procedures to the MDR, including:

- the timing of the applicability of obligations concerning the Eudamed database;
- the digitalisation and streamlining of all communications;
- the investigations into devices with and without European conformity labels; and
- any significant amendments to clinical investigations, which must be notified within one week to the Ministry of Health.

The publication of the European Delegation Law 2021 and the Ministry of Health communication are clear and tangible proof that Italy is reacting promptly to the introduction of the MDR.

For further information on this topic please contact Gloria Gelosa at Trevisan & Cuonzo by telephone (+39 02 86 46 3313) or email (ggelosa@trevisancuonzo.com). The Trevisan & Cuonzo website can be accessed at www.trevisancuonzo.com.