NEW EUDAMED GUIDANCE DOCUMENTS ON DATA EXCHANGE SOLUTIONS AND DATA EXCHANGE SERVICES

On 29 May 2019, the European Commission released a new batch of Eudamed guidelines on data exchange solutions and data exchange services. The following documents are now available:

- **Eudamed Data Exchange guidelines** (available here)

    This document aims to help competent authorities, notified bodies and all economical operators (*i.e.* manufacturers, authorized representatives, importers, and system/procedure pack producers) in assessing the most cost-efficient solution for their needs to comply with the Medical Device Regulation's ('**MDR**') future version of Eudamed. Although Eudamed offers multiple ways of inputting/downloading data, there are several parameters to take into consideration before making a decision.

    The document provides an overview of the requirements specific to the following data input methods:

    - The User Interface: this option implies manual input of data through the application. It is the simplest option in terms of data handling, manipulation and implementation as it only requires a PC and a browser to connect to Eudamed online.

    - The XLM upload/download: this option is a semi-automated one and is expected to be useful when Eudamed goes live to upload data in bulk using the XML format.

    - The Data Exchange Machine-to-Machine ('**M2M**') system: this option allows for automatic data exchange between an external backend system and Eudamed backend services. After entering information in the external system, the data is automatically transmitted to Eudamed in XML format without any human intervention. This is the most complex and costly solution and should only be considered under a specific set of conditions. Such conditions relate to whether the amount of data can be entered manually, frequent exchanges of information between systems are expected, cost of manual input versus cost of automation and resources for system implementation and maintenance.

- **Eudamed Data Exchange services and entity models introductions** (available here)

    This document addresses high-level architecture and data modeling to perform M2M Eudamed data exchange using the eDelivery building block of the Connecting Europe Facility. The introductory guidelines of the document seek to enable an interoperable exchange of electronic data and documents.

- **M2M Data Exchange services definition** (available here)

    This document defines types of M2M data exchange services, including basic unique device identification ('**UDI**') services.

We will inform you whenever new guidance documents become available. We selected this topic because of the relevance of Eudamed and the new MDR for dental dealers in the EU.

We hope this information is useful. You should not hesitate to contact us should you have any questions or require further information.

Kind regards,

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