A call to keep EUDAMED voluntary until it is mandatory to use

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MedTech Europe
from diagnosis to cure

Contents

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Introduction

Until EUDAMED[1] is fully operational, MedTech Europe urges all Member States to maintain current national processes. EUDAMED should be a voluntary alternative of complying with national registration requirements rather than the only way of complying with them[2].

Early voluntary use of EUDAMED can provide benefits for the medical technology industry such as the early access to the Single Registration Number (which is helpful for regulatory documentation purposes) and gaining experiences with the data submission before the mandatory deadlines set for the use of the central medical device database.

Industry is keen to start using the EUDAMED Device module extensively once it reaches a stable and validated state[3]. Industry members have challenges with registering devices systematically in the central medical device database, therefore it is premature either to strongly encourage or mandate by national law the exclusive use of EUDAMED. Regarding the Device registration module in particular, the database is not yet fully operational, and updates are still foreseen.

For the time being, a consistent and level playing field is needed for all manufacturers during this period of voluntary use. We encourage Member States to allow the use of EUDAMED as a voluntary means of complying with registration requirements to avoid double registration. However, the exclusive and mandatory (or strongly encouraged) use of EUDAMED should not be the only way to comply with national registration requirements.

The document describes below both the advantages and challenges of the early use of EUDAMED for the industry in order to support the call for EUDAMED to remain voluntary until it is declared fully operational.

Advantages to early use of EUDAMED for the industry

1. A number of national competent authorities accept registration in lieu of the national registration in their database. MedTech Europe supports the use of EUDAMED on voluntary basis to avoid duplications in national databases.
2. Registration in the Actor module, which has been available since December 2020, enables manufacturers to apply for Single Registration Number (SRN) ahead of the mandatory use of EUDAMED. The SRN can already be included in relevant MDR/IVDR documentation so there is no need to update regulatory documents at a later stage (Declaration of Conformity, Technical Documentation, Certificates issued by a Notified Body, Certificate of Free Sale).
3. It is valuable to gain experience with the data submission before the mandatory use of EUDAMED applies.

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[1] The official web address of the EUDAMED public website: "ec.europa.eu/tools/eudamed".

[2] The use of EUDAMED is not yet mandatory as per Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)[2]. The modules on Actor, Device (and Unique Device Identification) and Certificate registration are already available and can be used voluntarily. However, their use is not imposed by MDR and IVDR for any parties such as for Competent Authorities, Notified Bodies and Economic Operators.

[3] See the EUDAMED implementation plan of the European Commission's (June 2022): https://health.ec.europa.eu/system/files/2022-07/md_eudamed_timeline_en.pdf

Challenges to early use of EUDAMED for the industry - UDI and device registration (UDID) module

The systematic use of EUDAMED UDID module for manufacturers has some challenges:

1. While the UDI and device registration (UDID) module is available since Q4 2021, it is **still in development**. Also, there are interdependencies between the UDID module and other EUDAMED modules which have not yet been finalized.
2. Final **documentation** is not yet available. For example, industry is waiting for a complete list of which fields can be edited and how.
3. Not all industry users currently have **playground access to test machine-to-machine (M2M) capabilities** for mass data uploads.
4. For higher class devices, the registration is dependent on the applicable **Notified Body** also voluntarily completing their obligations in EUDAMED before the device will reach a "registered" status and displayed at the public site of EUDAMED.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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