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MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States

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This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745.
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MDCG Position Paper

on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States

Article 33 of Medical Devices Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (hereafter: 'MDR') sets out that the Commission, after consulting the MDCG, shall set up, maintain and manage the European database on medical devices (EUDAMED). EUDAMED shall be composed of multiple electronic systems (so called 'modules'), including an electronic system on registration of economic operators, also referred to as the **actor registration module**.

In accordance with Article 30(1) MDR, the actor registration module shall allow for the creation of a **unique single registration number ('SRN')** referred to in Article 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer (including producers of system/procedure packs) and, where applicable, the authorised representative and the importer. As such, the actor registration module forms a pre-requisite for the use of the other EUDAMED modules and facilitates a secure way of accessing EUDAMED. The responsibility to assign SRNs to economic operators lies with the Member States. To that end, Article 31(2) stipulates that, after having verified and validated the data entered by an economic operator, the competent authority of a Member State shall obtain an SRN from the actor registration module and approve the issuing of it to the requesting manufacturer, authorised representative or importer.

On 30 October 2019, the Commission published a notice by which it concluded that the full functionality of EUDAMED requires the availability and full operation of all six modules in accordance with the technical specifications and confirmed by an audit as referred to in Article 34. The notice foresees the launch of a fully functional EUDAMED for May 2022. However, at its meeting of 12 March 2020 the MDCG agreed that the Commission makes available to Member States each EUDAMED module on a gradual basis as soon as it is operational.

In line with the MDCG decision referred to above, the Commission has confirmed its readiness **to deploy the actor registration module as of 1 December 2020.** The members of the MDCG **strongly encourage the use of the actor registration module by all relevant actors on their territories, including the use of the single registration number** by actors as stipulated in the MDR (e.g. indicating the SRN on certificates).

The members of the MDCG agree that **double registration requirements for actors should be avoided as much as possible**. Therefore, actors that obtain an SRN should be considered in compliance with the actor registration requirements (for manufacturers, authorised representatives, importers, system/procedure pack producers) to the extent that national laws accommodate for this. In such cases, those actors should follow the obligations and requirements of the MDR related to both the registration of relevant actors (via the actor registration module) and the use of their SRN as required.