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Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR

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MDCG 2021-13 rev.1 changes
New Question 9

Introduction

This Q&A is a document aimed at addressing questions relating to the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 of Regulation (EU) 2017/745 on medical devices (MDR) and/or Article 28 of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR). It also clarifies the cases where an Actor ID is issued instead of an SRN.

This document should be read in conjunction with other relevant MDCG Guidance documents.[1]

Terminology

Actor ID: an Actor ID is the identifier issued to all actors registered in EUDAMED for their identification in the system. It will be automatically generated by EUDAMED and issued once the registration request is approved by the relevant competent authority.

SRN: a SRN is the Single Registration Number that is issued through EUDAMED to manufacturers, authorised representatives and importers by the competent authority in accordance with Article 31 MDR and 28 IVDR.

Legacy devices: This guidance follows the approach set out in Guidance MDCG 2019-5[2] according to which 'legacy devices' should be understood as devices, which, in accordance with Article 120(3) MDR and Article 110(3) IVDR, are placed on the market after MDR or IVDR dates of application respectively and until 26 May 2024, or until the relevant certificate becomes void, if certain conditions are fulfilled.

- devices which are class I devices under Directive 93/42/EEC, for which a declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body;
- devices covered by a valid certificate issued in accordance with Directives 90/385/EEC or 93/42/EEC prior to 26 May 2021;
- devices covered by a valid certificate issued in accordance with Directive 98/79/EC prior to 26 May 2022.

[1] All MDCG Guidance documents can be found on the European Commission Medical Devices website dedicated section.
[2] Guidance 'Registration of legacy devices in EUDAMED' – MDCG 2019-5

'Old' devices: devices placed on the market according to the medical devices Directives or the *in vitro* diagnostic medical devices Directive before the date of application of the MDR and IVDR or placed on the market before the Directives entered into force.

1. What is the procedure to register as actor in EUDAMED?

The procedure to register as actors in EUDAMED[3] will be laid down in a Commission Implementing Regulation on EUDAMED (in preparation), which will be applicable to all natural or legal persons registering to the system.

The actor registration request for any manufacturer, authorised representative, importer or a system/procedure pack producer should be verified and approved by a competent authority.

Please note that when an actor not subject to the obligations of Article 31 MDR and 28 IVDR submits an actor registration request in order to be able to report for the first time a serious incident or a field safety corrective action (FSCA), this actor should immediately provide information outside EUDAMED to the relevant national competent authority (ies) on the vigilance report and the pending actor registration request. It should also specify in the Actor registration form field "Any other information of significance for the competent authority" that the registration request is triggered by a need to report a serious incident or a field safety corrective action. After the approval of the actor registration request, the actor will have to submit those data to EUDAMED even if already communicated to the competent authority (ies) outside the system.

2. Do manufacturers of only custom-made devices have to register as actors in EUDAMED?

According to Article 31 MDR, manufacturers of only custom-made devices are exempted from the obligation of registering as actors in EUDAMED **before** placing their devices on the market.

However, the obligation to provide the information mentioned in Question 3 to EUDAMED applies to manufacturers of only custom-made devices. In order to be able to fulfil those obligations, they should register as actors in EUDAMED when such obligation to provide information occurs.

[3] For more information on how to use the Actor registration module, please refer to the document 'Guide to using EUDAMED – Actor registration module'.

3. When do manufacturers of only custom-made devices[4] have to register as actors in EUDAMED?

Articles 52(8), 56(1) and (5) MDR require notified bodies to enter the information regarding the certificates issued for class III custom-made implantable devices in EUDAMED. Moreover, manufacturers shall report in EUDAMED serious incidents,

field safety corrective actions and their related field safety notices (Article 87 MDR), any trend on non-serious incidents (Article 88 MDR) for custom-made devices[5].

Therefore, manufacturers of only custom-made devices have to register as actors in EUDAMED in the following cases:

- in advance of the entering of the information in EUDAMED by the notified body regarding the first certificate for their Class III custom-made implantable device;
- they submit to EUDAMED for the first time vigilance reports for serious incidents, field safety corrective actions with their field safety notices, or trend reports in respect of custom-made devices of any risk class;

The registration as actors in EUDAMED will be required, in the abovementioned cases, also for non-EU manufacturers of only custom-made devices and the authorised representatives for the concerned custom-made devices.

Registered manufacturers and authorised representatives of only custom-made devices are assigned an Actor ID that is not a SRN.

4. Do manufacturers of only legacy devices have to register as actors in EUDAMED?

Yes, manufacturers of only legacy devices[6] will have to register as actors in EUDAMED.

According to Article 123 (3) (d) MDR and Article 113 (3) (f) IVDR, the deadline for such registration is 6 months after the date of publication of the notice referred to in Article 34 (3) MDR. Member states may accept/require the use of EUDAMED for the purpose of registration in accordance with national rules, during the transition period.

The obligation to register as actors in EUDAMED is applicable also to non-EU manufacturers and authorised representatives of only legacy devices.

[4] For more information on custom-made devices, please refer to the document 'Questions and Answers on Custom-Made Devices' - MDCG 2021-3
[5] For more information, please refer to the document 'Questions and Answers on Custom-Made Devices' - MDCG 2021-3
[6] For more information, please refer to the document 'Management of legacy devices – MDR EUDAMED' and the Guidance 'Registration of legacy devices in EUDAMED' – MDCG 2019-5

Registered manufacturers and authorised representatives of only legacy devices are assigned an Actor ID that is not a SRN.

5. Do manufacturers of only 'old' devices have to register as actors in EUDAMED?

Yes, manufacturers of only 'old' devices, which are made available on the Union market and/or are still in use, will have to register as actors in EUDAMED in case serious incidents reports or field safety corrective actions in respect of the device are requested by the Member States to be reported in EUDAMED.

The obligation to register as actors in EUDAMED is applicable also, in the abovementioned cases, to non-EU manufacturers of only 'old' devices and their concerned authorised representatives.

In case either the manufacturer or the authorised representative is not active anymore, serious incidents and the field safety corrective actions will not be reported in EUDAMED and the manufacturer or authorised representative will not have to register as actor in EUDAMED.

Registered manufacturers and authorised representatives of only old devices are assigned an Actor ID that is not a SRN.

6. Do system and procedure pack producers (SPPP) have to register as actors in EUDAMED?

According to Article 29 (2) MDR, before placing a system or procedure pack on the market, the natural or legal person responsible (SPPP) has an obligation to assign a Basic UDI-DI to be provided to the UDI database, together with the other data referred to in Part B of Annex VI MDR.

In order to fulfil such obligation, as from 6 months after the date of publication of the notice referred to in Article 34 (3) MDR, the SPPP will have to be registered as actor in EUDAMED before placing a system or procedure pack on the market. Member states may accept/require the use of EUDAMED for the purpose of registration in accordance with national rules, during the transition period.

Registered SPPPs are assigned an Actor ID that is not a SRN.

7. Who is the authority responsible for the approval of actor registration requests of SPPP located in non-EU countries?

The authority responsible for approval of non-EU SPPPs actor registration requests should be the authority of the place where the first system or procedure pack of that producer is to be placed on the market. The CA may gather relevant additional information outside EUDAMED, when such information is not available inside EUDAMED, before validating a registration request.

Please note that SPPP located in a non-EU country do not have an obligation to designate an AR. Therefore, the SPPP should consider providing additional relevant information to the CA, in order to facilitate the verification of the data provided for the purpose of the registration request. In the "Any other information of significance for the competent authority" field, the SPPP should specify the reason for which that competent authority was chosen.

In case the non-EU SPPP acts also as a non-EU manufacturer, who has an authorised representative already designated, the authority responsible for the authorised representative should be the authority responsible for the approval of the non-EU SPPP actor registration request.

8. When the Actor ID may be considered as a Single Registration Number (SRN) pursuant to Article 31 MDR and Article 28 IVDR?

The Actor ID will only be considered as a SRN when it will be issued to a manufacturer or authorised representative or importer of MDR non-custom-made devices and/or of IVDR devices, as referred to in Article 31 MDR and 28 IVDR.

In case it is issued to a manufacturer (EU and non-EU) or authorised representative or importer of only custom-made devices and/or only legacy devices and/or only 'old' devices or to a system/procedure pack producer, this Actor ID will not be considered as a SRN pursuant to Article 31 MDR and 28 IVDR.

As a consequence, manufacturers, authorised representatives and importers may have an Actor ID that will be considered also as a SRN when, after their registration in EUDAMED, they become manufacturers, authorised representatives and importers of MDR non-custom-made devices and/or of IVDR devices.

For example, in case a manufacturer of only custom-made devices extends its activities and becomes a non-custom-made devices manufacturer (or an IVDR manufacturer), its Actor ID will be considered its SRN.

9. Do importers who carry out the activities mentioned in Article 16 MDR/IVDR also need to register as manufacturers in EUDAMED?

On one hand, importers who assume the obligations incumbent on manufacturers according to Article 16(1) MDR/IVDR, as clarified in MDCG 2018-6, have the obligation to register as Manufacturers in EUDAMED.

On the other hand, importers who carry out the activities mentioned in Article 16(2) MDR/IVDR do not have any obligation to register as manufacturers in EUDAMED since these activities are not considered a modification of a device that could affect its compliance with the applicable requirements, so they do not act as a manufacturer.

In any case, importers are subject to the obligation of registering as Importers in EUDAMED in accordance with Article 31 MDR and 28 IVDR. This registration is due to the fact that the importer places the devices on the EU market, and is not due to the fact that he carries out the activities mentioned in Article 16 (2) MDR/IVDR (namely, relabelling or repackaging of devices).