The Medical Devices Regulation (MDR) EU 2017/745 came into effect on 26 May 2021. Article 120 of MDR has specific transitional provisions in relation to medical devices that continue to be placed on the market under the Medical Devices Directive (MDD) 93/42/EEC (legacy devices).

According to the transitional provisions of article 120, legacy devices may continue to be placed on the market or put into service until 26 May 2025 **if** they continue to meet the requirements of the aforementioned legislation and **there are no significant changes in their design and/or intended purpose**. For additional guidance on what constitutes a significant change in design or intended purpose please refer to MDCG 2020-3: https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_guidance_significant_changes_annexes_en.pdf

Manufacturers of legacy devices shall comply with transitional requirements that apply form 26/05/2021 relating to:

- All economic operators – manufacturers, importers to European Union and Authorized Representatives – of medical devices shall be registered to European Databank on Medical Devices -EUDAMED.
- post-market surveillance
- market surveillance
- vigilance

Those requirements from MDR should apply even if the devices are not being transitioned to MDR.

ACTIONS TO BE APPLIED BY MANUFACTURERS

Manufacturers of legacy devices- including manufacturers of procedure packs/systems shall take the following actions:

1. Register in EUDAMED (till September 2021) as actors. For additional guidance on how to use EUDAMED – Actor registration module please refer to the relevant guide:

   https://ec.europa.eu/health/sites/default/files/md_eudamed/docs/md_user_guide_actor_module_en.pdf).

2. Get a SRN (single registration number) from Competent Authority that issues the generated from EUDAMED SRN after approving the registration request. SRN is sent from EUDAMED through e-mail.
   Products can be registered in EUDAMED, **if desired** by the manufacturer only after the approval if the relevant SRN. Registration in national registries depends on national provisions.

   Information relevant to the registration of products in EUDAMED.

   *Legacy Devices shall be registered in EUDAMED **in two cases**:*

   *I) **Obligatory**, if a post-market surveillance and/or a vigilance report occurs - for example if there is a safety notice (FSCA) in 15 days and if there is a threat (serious incident) in 2days time. In any case, registration should be done as soon as possible and at least before a follow up or final vigilance report is submitted.*

For more information, please refer to MDCG 2019-5 Registration of legacy devices in EUDAMED: https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2019_5_legacy_devices_registration_eudamed_en.pdf).
II*) within 24 months after the day of publication of the notice by the European Committee for the full functionality of EUDAMED (expected on May 2022), if no equivalent MDR device is registered in EUDAMED.*

The assignment of a Basic UDI-DI and UDI-DI is not required for a Legacy Device. *Nevertheless, if the manufacturer desires to register its products on EUDAMED, in order to keep the same standard structure and identification elements for all devices registered in EUDAMED, an identification element* ***EUDAMED DI*** *(the equivalent of the Basic UDI-DI) will be required, and a EUDAMED ID (in case no UDI-DI has been assigned) will be generated from the EUDAMED DI.*

On the other hand, a UDI-DI can be used to identify a Legacy Device in EUDAMED. Moreover, only one device identifier will be assigned to a Legacy Device, either a UDI-DI (where the EUDAMED DI is automatically generated) or a EUDAMED DI (where the EUDAMED ID is automatically generated).
For more information on EUDAMED-DI and UDI-DI generation please refer to

- guideline: MANAGEMENT OF LEGACY DEVACES MDR EUDAMED 15.02.21 https://ec.europa.eu/health/sites/default/files/md_eudamed/docs/legacy_dvc_management_en.pdf

- issuing entities of UDIs : https://eu-udi.zendesk.com/hc/en-150/articles/360019532878 Who-are-and-who established-the-issuing-entities ON -LINE EA
- You can also check UDI helpdesk on the following link: https://eu-udi.zendesk.com/hc/en-150

Furthermore, there are several online applications for EUDAMED DI generation, some of them are for free.

3. Create or update (if existed) the PMS and PMCF (post market clinical follow-up)– according to the requirements of MDR.
   For more information about the MDR requirements on post-market surveillance please refer to Articles 83-86, Annex III and Annex XIV Part B, for market surveillance refer to article 93-99 and for vigilance refer to articles 87-90.
   Two guidance documents, in the form of templates, have been made available on the European Commission website, one on PMCF plans and the other on PMCF reports. The two guidances are:
   - MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template. A guide for manufacturers and notified bodies https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2020_7_guidance_pmcf_plan_template_en.pdf) and
   - MDCG 2020-8 Post-market clinical follow-up (PMCF) Evaluation Report Template. A guide for manufacturers and notified bodies https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2020_8_guidance_pmcf_evaluation_report_en.pdf)

According to Article 86, PSURs should submitted to the Notified Body at a time depending on the product's classification.

Furthermore, according to the Article 15 the person responsible for regulatory compliance (PRRC) for manufacturers and European Authorized Representatives has some responsibility for PMS, MS, vigilance, registration of economic operators and registration of devices. The requirements for legacy devices, in relation to the above, could be met by the appointment of a competent person, however its establishment is not mandatory.

Finally, the MDCG 2021-25 "Regulation (EU) 2017/745 - Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC", that has been issued recently (October 2021) has summarized the aforementioned requirements that are expected to be met during surveillance audits for legacy devices. (available in the following link: https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_25_en.pdf)