# Interim measures applicable in the absence of MDR EUDAMED

## Executive summary by joint industry associations

6 March 2020

The undersigned industry associations prepared this executive summary to address transitional provisions in the absence of EUDAMED. This analysis is based primarily on legal and on pragmatic aspects of the implementation of the Medical Devices Regulation 2017/745 ('the MDR').

We are sharing this document with MDCG members in order to achieve interim measures that are to be implemented proportional to the objective (i.e. providing interim solutions until EUDAMED will be launched). These measures should not impose extra burden on any impacted parties and should not exceed the existing requirements for data exchange.

We regret that a fully functional EUDAMED will not become available by date of application of the MDR as we value transparency as a significant improvement brought by MDR if implemented in a meaningful - validated, central and coordinated - manner.

Until EUDAMED is fully functional, the industry believes in taking the following actions:

1. We see value in the deployment of the Actor registration module and subsequent modules once they are ready for deployment on a voluntary basis provided that they are supported by all National Competent Authorities. For the actor registration it should be guaranteed that the information and issued SRN remains stable (the same) so no double or additional actor registration is required either before (at national level) or after EUDAMED go-live.

2. In the absence of EUDAMED, information to be provided should be limited to what is expected by the Medical Device Directives under the national databases of today. The upcoming guidance document should not require operators to upload additional MDR-specific information at a national level.

3. We will undertake the preparation of documents and reports as legally required and specified by the MDR and their submission to the relevant parties, as foreseen in the MDR.

4. We call for consistent transitional regime that will not require retrospective submission into EUDAMED of reports or data that have already been provided to relevant parties.

| Activities triggered by the absence of a fully functional EUDAMED (or its modules) in the interim period | | |
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| **Module / requirement** | **Industry supports** | **Industry should not be required to** |
| **Registration of actors** | ✓ Continuation of registration of manufacturers and authorized representatives as under the Directives<br>✓ Release of the Actor module on a voluntary basis provided that it is supported by all National Competent Authorities and that it remains stable. | × Register economic operators in national databases if already done voluntarily in the Actor module of EUDAMED<br>× Change Single Registration Number or add extra information as a condition for use the Single Registration Number when a fully functional EUDAMED goes live |
| **Device Verification by actors*** ** applicable for MDR products only, not for legacy devices* | ✓ Verification of the Declaration of Conformity and Technical Documentation by Authorised Representatives<br>✓ Verification of CE Mark, Declaration of Conformity, labeling and UDI by Importers | × Verify the Manufacturer Device Registration as an Authorised Representative<br>× Verify the Device Registration as an Importer<br>× Add Importer information to Device Registration |
| **Registration of devices** | ✓ Continuation of device registration as under the Directives<br>✓ If legally required, preparation of the master Summary of Safety and Clinical Performance (SSCP) | × Register new (additional) device data elements only required under the MDR<br>× Translate Summary of Safety and Clinical Performance unless individually and specifically requested by a competent authority.<br>× Publish Summary of Safety and Clinical Performance (not a manufacturers' responsibility as per MDR) |
| **Unique Device Identification (UDI)** | ✓ Assignment of Basic UDI-DI and UDI-DI for MDR-compliant devices and inclusion in the relevant | × Register new device data, UDI core data only required under the MDR in national databases |

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| | regulatory documentation (Technical Doc, Declaration of Conformity, Certificates, ….) | |
| **Labelling** | ✓ Affixing UDI-carriers as per the MDR timelines on MDR-compliant devices<br>✓ Referencing a link to EUDAMED public site in the Instruction for Use to locate Summary of Safety and Clinical Performance | × Update Instruction for Use due to EUDAMED availability i.e. change the link to EUDAMED public site referenced in Instruction for Use to locate Summary of Safety and Clinical Performance |
| **Vigilance** | ✓ Continued use of current forms and report submission to authorities as under the Directives – Manufacturer Incident Reporting (MIR), Field Safety Corrective Action (FSCA), Field Safety Notice (FSN), Trend Reporting<br>✓ Comply with applicable reportability criteria and timelines as under MDR | × Retrospectively upload or update reports upon EUDAMED availability that already have been provided |
| **Post-Market Surveillance** | ✓ Preparation and submission of Periodic Safety Update Report to Notified Bodies as applicable | × Retrospectively upload or update Periodic Safety Update Report upon EUDAMED availability that already have been provided |
| **Clinical Investigation** | ✓ Continuation of the Clinical Investigation application with current processes as under the Directives at individual authorities<br>✓ Continued use of Serious Adverse Event reporting form and process as under the Directives, and compliance with applicable reportability criteria as under MDR | × Retrospectively upload or update Clinical Investigation applications and reports upon EUDAMED availability that already have been provided |