Mecomed Medical Technology Association
Middle East and Africa

Executive Office No. 9 | Floor 5 | DHCX | Building No.64
Dubai Healthcare City | United Arab Emirates

mecomed.com

To: Regional Health Authorities in Middle East and Africa

Subject: Impact of the IVDR and MDR Amendment on countries recognizing EU CE marking

The purpose of this communication is to provide an overview of the European Regulation (EU) 2024/1860 of 13 June 2024, amending **Regulations (EU) 2017/745 and (EU) 2017/746** as regards a gradual roll-out of Eudamed (European Database on Medical Devices), information obligation in case of interruption of supply, and the transitional provisions for certain in vitro diagnostic medical devices (IVDs).

One of the goals of Regulation (EU) 2024/1860 is to maintain patients' access to a wide range of IVDs while ensuring a smooth transition to the new regulatory framework and to allow enough time for the certification process.

When it comes to the IVDR, the main feature of this amending regulation was providing an extension of the IVDR transitional period per risk class for IVDs meeting certain conditions. Most devices with certificates or declarations of conformity issued under the Directives may continue to be placed on the market after the respective dates of application of the Regulations (MDR/IVDR) until the end of the relevant transition period. Therefore, **devices that are compliant with the previously applicable Directives and devices that are compliant with the current Regulations coexist and may be placed or made available simultaneously on the EU market** ".

Which IVDs are in scope of this extension?

- Devices with IVDD certificate issued from 25 May 2017 and valid on 26 May 2022, which was not withdrawn afterwards.
- IVDs that did not require the involvement of NB under the IVDD (commonly known as IVDD self-declared devices) but do so under IVDR may continue to be placed on the market or put into service until 31 December 2029 at the latest, depending on the risk class of the device.

No transition period applies to IVDs that do not require the involvement of a notified body under the IVDR (i.e. class A non-sterile IVDs). Similarly, all 'new' IVDS, ie devices not previously covered by a certificate or DoC issued under the IVDD, cannot benefit from the extended IVDR transitional provisions.

What are the new deadlines?

The above-mentioned IVDs benefit under Regulation (EU) 2024/1860 from extended staggered transition periods to be certified under the IVDR depending on the risk class as follows:

- **31 December 2027** for devices covered by IVDD certificates and which are class D devices under the IVDR.
- **31 December 2028** for class C devices under the IVDR.
- **31 December 2029** for class B and class A sterile devices under the IVDR.

What are the conditions to meet to benefit from the deadline extension?

In order to be eligible to the extension, the manufacturer needs to ensure:

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- Continuous compliance with IVDD (The IVD Directive)
- There are no significant changes in design/intended purpose
- Devices do not present an unacceptable risk to health/safety
- Meeting IVDR requirements related to post market surveillance, vigilance, and registration of economic operators and devices.
- Having an IVDR QMS in place by 26 May 2025
- Having an IVDR Application for conformity assessment lodged by:
  - ✓ by 26 May 2025, for devices covered by IVDD certificate and class D devices
  - ✓ by 26 May 2026, for class C devices
  - ✓ by 26 May 2027, for class B and class A sterile devices
- Having an agreement with the Notified Body signed by:
  - ✓ by 26 September 2025, for devices covered by IVDD certificate and class D devices
  - ✓ by 26 September 2026, for class C devices
  - ✓ by 26 September 2027, for class B and class A sterile devices

What are the documents proposed by the EU Commission to confirm that the IVD complies with the extended transition:

- Manufacturer's self-declaration for IVDR
- Notified Body Confirmation Letter (optional) and can only be issued after a written agreement has been signed between NB and Manufacturer, by the applicable deadline in Sep 2025, Sep 2026 or Sep 2027 (based on risk class)
- Certificate of Free Sale (optional and on request)

Furthermore, it is important to note that most legacy IVDs do not have IVDD certificates, but where they do, legacy IVDs with IVDD certificates which are *not* transitioning to IVDR, still can benefit from the extended transition times specified in (EU) 2022/112 until May 2025 or until the expiry date of the certificate, whatever comes first. This is confirmed by the European Commission Q&A, question 3. The link to this document can be found in the Annex of this document.
Similarly, self-declared IVDD devices, which are not covered by an IVDD certificate, and which are *not* transitioning to IVDR, can still benefit from the transition timelines as specified in (EU) 2022/112:

- 26 May 2025, for class D devices under the IVDR
- 26 May 2026, for class C devices under the IVDR
- 26 May 2027, for class B and class A sterile under the IVDR

As per the amending regulation (EU) 2024/1860, the extension of the certificate's validity is done automatically by law, even if the date on the certificate might show as being expired. This is confirmed by the European Commission Q&A question 5. The link to this document can be found in the Annex of this document.

Furthermore, the documents listed above can be used to confirm the extension of the certificates' validity **when the date on the certificate shows as expired**. In particular, **the manufacturers' self-declaration is intended as the primary tool** to demonstrate that manufacturers and devices are compliant with the conditions to benefit from the extension. The Manufacturer's declaration as per

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the template published by the European Commission is quite detailed and provide sufficient information to the regulators relying on the CE Mark, on the eligibility of respective products for the extended transition period.

In order to raise awareness of this Amendment for International Markets, the EU Commission has updated its Fact Sheet for competent authorities in non-EU/EEA countries and hosted a webinar in July 2024 to provide **regulatory authorities in third countries** with clarifications on the recent updates, transitional provisions, and the current state of play of the regulatory framework for medical technologies in the EU

The link to the recording of the webinar and the updated Fact Sheet can be found in the Annex of this document.

As the amendment comes as an urgent relief, ensuring continuity of supply of diagnostics in the EU, we recommend the markets in our region, which recognize the EU CE marking to consider a pragmatic solution and align with the EU proposed documentation and timelines. This would allow a continued supply of IVDs to the patients in MEA region.

Annex – Link to EU Commission Supporting Documents

Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR,

Q&A on the extension of the MDR transitional periods

Fact Sheet for competent authorities in non-EU/EEA countries

Recording of EU Commission Webinar for competent authorities in non-EU/EEA Countries

Manufacturer's Declaration in relation to Regulation (EU) 2024/1860 - MedTech Europe