MAI. 22

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

European Regulation on in vitro diagnostic medical devices

Regulation (EC) 2017/746 of 5 April came into force on 26 May 2022 and it establishes the regulatory framework for in vitro diagnostic medical devices (IVDs). In doing so, it replaces the previous regulations in Directive 98/79/EC of 27 October 1998.

From this date, no evaluation of IVDs or issuance of a certificate of conformity can be carried out under Directive 98/79/EC, and IVDs are categorised as follows:

- "Old" devices - IVDs manufactured and placed on the market in compliance with the previous regulatory framework of the Directive.
- "Legacy" devices - IVDs with CE certificate and CE marking issued under the Directive that may continue to be made available on the market if they meet the requirements set out in Article 110(1) of the Regulation.
- "New" devices - IVDs placed on the market or put into service as from 26 May 2022 in accordance with the requirements of the Regulation.

The IVD rules define the type of obligations to be observed by manufacturers, importers and other participants in the IVD circuit from this date.

1. "OLD" IVDs

For "old" IVDs there is no obligation to comply with the requirements of the Regulation, except for the provisions on (i) post-market surveillance, (ii) market surveillance, (iii) vigilance and (iv) registration of economic operators and devices, which apply in place of the Directive's provisions applicable in these matters.

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Regulation (EC) 2017/746 of 5 April came into force on 26 May 2022 and it establishes the regulatory framework for in vitro diagnostic medical devices (IVDs).

There are two points to note regarding the validity of the certificates issued for "old" IVDs:

- Certificates issued by bodies notified before 25 May 2017 remain valid until the end of the period indicated in the certificate, except for certificates issued under Annex VI of Directive 98/79/EC, which become void by 27 May 2025 [1].
- Certificates issued by notified bodies under Directive 98/79/EC as of 25 May 2017 become void by 27 May 2025.

The notified body that issued the certificate will remain responsible for the appropriate surveillance of compliance with the applicable requirements (of the Regulation) with regard to all the devices it has certified.

"Old" devices placed on the market before 26 May 2022 may continue to be made available on the market or to be put into service until 26 May 2025.

Certificates issued by bodies notified under Directive 98/79/EC before 25 May 2017 will remain valid until the end of the period indicated in the certificate, except for certificates issued under Annex VI to Directive 98/79/EC which will become void at the latest on 27 May 2024. Certificates issued by notified bodies under Directive 98/79/EC as of 25 May 2017 become void by 27 May 2024.

The notified body that issued the certificate will remain responsible for the appropriate surveillance of compliance with the applicable requirements (of the Regulation) with regard to all the devices it has certified.

2. "LEGACY" IVDs

Devices classified as "legacy" may continue to be placed on the market or enter into service after 26 May 2022, provided that (i) they continue to meet the requirements of the Directive and (ii) their design and intended purpose have not been significantly changed.

The European Commission has published guidelines [2] that allow those involved in the IVD circuit to determine what are considered to be "significant changes" for this purpose [3]. Based on these guidelines, significant changes may include changes that determine the extent of the target population and the purpose of the IVD, a change in the user of the IVD, a change in a material that adversely affects its safety and performance, or changes in the sterilisation method.

In turn, the following are not considered to be "significant changes" for this purpose: (i) limitations on the intended purpose of the IVD, (ii) editorial changes, (iii) changes resulting from corrective actions considered acceptable by the competent authority, (iv) bug fixes and security updates, (v) changes in the appearance of the interface, (vi) replacement of a preservative (no impact), or (vii) changes to parameters in the sterilisation cycle.

1 It should be noted that, due to the Covid-19 crisis and the importance that IVDs play in combating this pandemic, the dates of application of the Regulation have been postponed by Regulation (EU) 2022/112 of 25 January 2022.

2 Available for consultation here.

3 Available for consultation here.

"Legacy" devices for which the conformity assessment procedure pursuant to Directive 98/79/EC does not require the intervention of a notified body, which have a declaration of conformity pursuant to that Directive issued before 26 May 2022 and for which the conformity assessment procedure pursuant to this Regulation requires the intervention of a notified body, may be placed on the market or put into service until the following dates:

- 26 May 2025 - class D devices;
- 26 May 2026 - class C devices;
- 26 May 2027 - class B devices; and
- 26 May 2027 - class A devices placed on the market in a sterile condition.

All other "legacy" devices placed on the market as from 26 May 2022 may continue to be made available on the market or to be put into service until the following dates:

- 26 May 2026 - devices whose certificate was issued in accordance with Directive 98/79/EC and class D devices referred to in the previous paragraph;
- 26 May 2027 - class C devices referred to in the previous sub-paragraph;
- 26 May 2028 - class A and B devices referred to in the previous sub-paragraph.

As from 26 May 2022, those involved in the "legacy" IVD circuit must have implemented a post-marketing surveillance system based on a plan that includes post-market performance follow-up requirements.

As from 26 May 2022, those involved in the "legacy" IVD circuit must have implemented a post-marketing surveillance system based on a plan that includes post-market performance follow-up requirements. Manufacturers must also assess the performance of the IVDs they place on the market, and report serious incidents of which they are aware and the corrective actions they implement. They must also draw up a trend report and the post-marketing monitoring report, and carry out market surveillance.

3. "NEW" IVDs

As for "new" devices, which will now be made available under the new rules of the Regulation, the obligation of the Manufacturer to provide a UDI (unique device identification) is one of the main changes introduced by the Regulation.

Also of note is the extension of responsibility for the UDI to all participants in the circuit. All other participants, whether the representative, importer or distributor, now have the responsibility to check that the device has the UDI assigned by the manufacturer. The representative and importer are also responsible for verifying that the medical device is registered in the EUDAMED database.

Given their low risk, IVDs in class A do not require the intervention of the notified body for a conformity assessment before being placed on the market or put into service.

In view of the change to the IVD risk classification model defined by the Regulation, it is important to ensure a reassessment of IVDs to ensure that their current classification is in line with the classification defined in the Regulation. In this procedure, it will be important to define precisely the intended purpose of the IVD. The risk classes will be organised from class A to class D, with class A IVDs being those with lower risk and class D those with higher risk.

Given their low risk, IVDs in class A do not require the intervention of the notified body for a conformity assessment before being placed on the market or put into service.

The risk assessment process must be done according to ISO 14971 ("Application of Risk Management to Medical Devices"). ■

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