MedTech Europe
from diagnosis to cure

PRESS RELEASE

MedTech Europe welcomes the *In Vitro* Diagnostic Medical Devices Regulation and urges continued work to deploy the new regulatory system

Urgent solutions for the certification of new, innovative tests greatly needed and expected by patients

26 May 2022, Brussels – Today's date of application of the *In Vitro* Diagnostic Medical Devices Regulation (IVDR) marks an important new chapter for *in vitro* diagnostic (IVD) medical tests in Europe. Since the publication of the IVDR five years ago, the IVD manufacturing sector has fully supported its goals, investing significant resources into complying with its requirements and ensuring that IVD medical tests remain available to patients, healthcare professionals and laboratories.

The IVDR represents a revolutionary overhaul of the regulatory requirements: a strengthened notified body system which must assess about 70% of IVDs for the first time, a new risk classification system, updated clinical evidence requirements, a new post-market system, a new database enabling more transparency (EUDAMED), a unique device identification system facilitating supply chain traceability, and more.

"*Today as we welcome the full application of the IVD Regulation, the medical technology industry stands ready to continue collaborating with all actors, to ensure the timely and smooth transition of all IVDs to its updated requirements. The new IVD Regulation promises a modernised certification system which our sector is committed to help succeed*", says Serge Bernasconi, CEO of MedTech Europe.

While much progress was achieved in preparing the new infrastructure over the past five years, some key pillars are still not fully operational or even in place. For this reason, the IVD Regulation was amended in January 2022 and granted most IVDs – depending on their risk class – three to five more years to transition to the new Regulation if they comply with certain conditions.

The amendment has not addressed all challenges, however. Today, as we mark the 26 May 2022 date of application, the incomplete IVDR infrastructure poses critical ongoing risks that need urgent resolution, e.g.:

- to ensure both innovative and updated devices can be certified under the IVDR and reach patients and healthcare systems.
- to make the regulatory systems fully operational to certify the highest risk IVDs and companion diagnostics (including those needed to manage infectious diseases and diagnostics to support personalised medicines).
- to urgently designate and build considerably more Notified Body capacity to support certification of all IVDs and reduce the long and unpredictable certification timelines we have today.
- to build other system infrastructure needed to implement the IVDR including requirements for performance studies, post-market, vigilance and EUDAMED database, etc.

Until these challenges are resolved, the IVD Regulation will not constitute a sufficiently predictable and reliable pathway to certification of needed medical tests. Such challenges need ongoing attention and work by the EU Commission and Medical Devices Coordination Group, if Europe is to ensure a workable system both today and over the longer term.

Finally, the Medical Devices Regulation (MDR) has been in full application for 12 months. As with the IVDR, the medical technology industry fully supports the new regulatory regime for MDs but due to many factors, the system is not yet ready to support its implementation. Urgent and pragmatic solutions prior to the end of the transition period in May 2024 are needed here as well to safeguard access to the needed medical devices.

"*Due to the complexity of the IVD and MD Regulations, it is critical that all needed infrastructure is put in place and made operational without delay. Above all, industry needs a conformity assessment system which is both fully in place and predictable to ensure innovative tests, routine tests and critical medical technology innovations remain available to our healthcare systems."* adds Serge Bernasconi.

MedTech Europe will continue to work with the EU institutions and stakeholders to rapidly propose solutions to avoid disruptions in the supply of life-saving diagnostics and medical devices.

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About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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