beMedTech welcomes the *In Vitro* Diagnostic Medical Devices Regulation.

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.

beMedTech will continue to work with the Belgian competent authorities FAMHP and other stakeholders, to ensure a smooth implementation of the IVD Regulation in Belgium.