COCIR Statement

Adoption of the EU Medical Devices Regulations extended transitional provisions

COCIR, which represents the united industry voice of the Medical Device manufacturers in medical imaging, radiation therapy and digital health sectors, welcomes the adoption of the extended transitional provisions for Regulations (EU) 2017/745 on medical devices (MDR) and (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). The temporary risk-based extension of transitional periods has proved necessary to counteract bottlenecks in the supply of Medical Devices and in MDR certification towards 2024, ensure access to the market to all already established and safe devices and, ultimately, guarantee continuity of patient care across Europe.

To ensure a smooth extension of certificates and the continued provision of safe Medical Devices during the transitional period, important details on the practical implementation of the new provisions must be clarified as soon as possible. In this regard, COCIR is looking forward to contributing to the Medical Devices Coordination Group webinar, taking place on 13 March, to jointly elaborate an effective and efficient implementation of the amendments.

COCIR stands ready to support the Medical Devices Regulation implementation and reiterates the importance of the transition to and compliance with its requirements to guarantee access to safe devices and the continuum of health care provision for European citizens.

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