PRESS RELEASE
(under embargo until 2pm today)

Medical Device Regulation Adopted

BRUSSELS – 5 April 2017: COCIR welcomes the adoption of the Medical Device Regulation (MDR) after successful vote during the European Parliament Plenary Session today. These new rules should allow for continuing improvement to the safety of medical devices, benefitting patients and ensure timely access to innovative healthcare technology.

In 2012, the European Commission set out to revise the legislative framework for medical devices to keep pace with both the rapidly-changing technological environment and specific challenges. Following four years of debate and discussion, we believe that the MDR will increase consistent interpretation across Member States, supporting a transparent regulatory framework. It will enhance traceability through a unique identification number and a central database, which will be accessible to all stakeholders. It also provides a stronger mandate for notified bodies and oversight for national authorities and enhanced responsibilities for manufacturers and other economic operators.

However, the most critical aspect for ensuring the timely access of patients to innovative medical devices is the successful implementation of the Regulation. Therefore, COCIR looks forward to continuing to support the European Commission and Member States during this critical phase. COCIR is ready to provide support during development of the corresponding delegated and implementing acts.

Nicole Denjoy, COCIR Secretary General, says "COCIR members that provide innovative technologies and services believe that the ongoing innovation in medical devices will continue to contribute significantly to the health and well-being of EU citizens. Medical technologies sectors covered by COCIR provide solutions covering the entire continuum of care, from diagnosis, through prevention, monitoring, treatment, alleviation to aftercare." She adds, "This is why the European regulatory framework should continue its evolution, providing the foundation for safe and effective medical technologies to come to market in synchronisation towards global regulatory convergence. Good regulations should work to both enhance patient safety and help innovative solutions reach the market in a timely manner, helping avoid unnecessary administrative burdens that could potentially increase overall costs and prevent citizens and patients from realising the full benefits".

COCIR is committed to working with regulators and all stakeholders in supporting a seamless transition from the Medical Device Directive to the Medical Device Regulation. This will ensure that patients across the EU continue to benefit from timely diagnoses and access to the latest advances in medical technology.

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**COCIR is the European Trade Association representing the medical imaging, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.*

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