

The AI Act needs to go hand in hand with sectoral legislation to keep AI-enabled products on the EU market

30 September 2022

Brussels, 30 September 2022 – In a joint statement, industry stakeholders call for the alignment of the proposed AI Act with sector-specific product safety legislation. If issues of overregulation and misalignment are not addressed, the resulting regulatory uncertainty could adversely impact the access of European citizens to safe and high-quality goods ranging from medical technologies, machinery and tools used in the automotive and furniture sector to gardening tools and machines protecting against electric fires.

The proposed Artificial Intelligence Act (AI Act) builds on the legal architecture of the New Legislative Framework (NLF) that serves to improve the safety and quality of products accessing the European market.

Stakeholders representing, among others, the machinery and medical technology industry point out in a joint statement released today that the proposal in its current form, however, significantly risks overregulating industries. If not addressed adequately, the duplicative requirements it creates could limit a wide range of products and technologies to access the EU market.

In the case of medical technologies, this could have a significant impact on manufacturers that are already under significant regulatory strain.

"Meeting the requirements of our own sectoral regulation under the NLF has required heavy lifting from the medical technology industry, but also for the Notified Bodies, where we currently see the biggest bottleneck. The impact of additional requirements from the AI Act would have manufacturers facing further technical and financial burdens as well as capacity constraints to get devices certified for the European market. We need to avoid this regulatory fragmentation, which could adversely impact patients' access to innovative healthcare solutions", said MedTech Europe CEO Serge Bernasconi.

The statement's signatories support the NLF provisions as a means of complying with the AI Act. However, when shaping and negotiating the AI Act, EU legislators should ensure that the requirements set out in this regulation will align closely with existing obligations in sector-specific legislation.

MedTech Europe, together with the other industry stakeholders, are committed to continuing constructive dialogues on this issue with legislators to help build a proportionate and well-functioning regulatory system that enables a trustworthy AI regulatory framework and seamless access of safe and high-quality products to the European market.

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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.

www.medtecheurope.org.

The statement has been co-signed by:

APPLiA

APPLiA, Home Appliance Europe is a Brussels-based trade association that provides a single, consensual voice for the home appliance industry in Europe. By promoting innovative, sustainable policies and solutions for EU homes, APPLiA, in conjunction with its 24 direct member companies and 26 National Associations, has helped build the sector into an economic powerhouse, with an annual turnover of €67 billion, investing over €1.4 billion in R&D activities and creating nearly 1 million jobs."

www.applia-europe.eu

CAPIEL

CAPIEL is the European Coordinating Committee of Manufacturers of Electrical Switchgear and Controlgear. CAPIEL represents 9 national associations from 8 European countries. CAPIEL member associations include small, medium and large-sized companies representing more than 100,000 direct jobs across the EU. CAPIEL membership includes global players.

www.capiel.eu

CECIMO

CECIMO represents globally the common position of European Machine Tool Industries and related Manufacturing Technologies, and promotes co-operation with other organisations worldwide.

www.cecimo.eu

CECIP

CECIP is the European association representing the weighing instrument industry. Founded in 1958, CECIP has currently members in 14 countries. The weighing instrument industry in Europe is world leader and consists of around 700 companies that are mostly SMEs. The total turnover is approximately 3 billion euro and the industry employs about 50.000 persons.

www.cecip.eu

COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, 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. We provide a wide range of services on regulatory, technical, market

intelligence, environmental, standardisation, international and legal affairs. COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association.

www.cocir.org

EFIC

EFIC is the European Furniture Industries Confederation, representing over 70% of the total turnover of the European Furniture Industries, a sector employing 1 million people in about 120.000 enterprises across the EU and generating a turnover of over 100 billion Euros. The EFIC membership is composed of 17 national associations, one individual company member and several clusters.

www.efic.eu

EGMF

The European Garden Machinery industry Federation – EGMF – has been the voice of the garden machinery industry in Europe since 1977. With 30 European corporate members and 7 national associations representing manufacturers for garden, landscaping, forestry and turf maintenance equipment, we are the most powerful network in this sector in Europe. Our members are responsible for employing 120,000 people in the EU, and in 2021 sold over 23 million units on the European Market.

www.egmf.org

EUnited

EUnited, the European Engineering Industries Association, is the voice of machinery and equipment suppliers in Europe. EUnited connects machinery and equipment companies in one association to improve awareness and understanding among decision-makers and policy actors in the European Union institutions and to articulate the role of equipment suppliers in technical standards development, policy formulation, trade issues and legislation. Equipment suppliers are the mainstay of advanced manufacturing, increasingly recognized as indispensable for basic needs.

www.eu-nited.net

Euralarm

Euralarm represents the electronic fire and security industry, providing leadership and expertise for industry, market, policy makers and standards bodies. Our members make society safer and secure through systems and services for fire detection and extinguishing, intrusion detection, access control, video monitoring, alarm transmission and alarm receiving centres. Founded in 1970, Euralarm represents over 5000 companies within the fire safety and security industry valued at 67 billion Euros. Euralarm Members are national associations and individual companies from across Europe

www.euralarm.org

EUROPGEN

Europgen promotes the interests of the European generating set industry in its relations with customer, suppliers, European regulatory authorities, and government organizations.

www.europgen.eu

MedTech Europe

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www.medtecheurope.org

Orgalim

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU's largest manufacturing sector, generating annual turnover of over €2,480 billion, manufacturing one-third of all European exports and providing 10.97 million direct jobs.

www.orgalim.eu

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