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European medical technology industry calls for the EU to join the Medical Device Single Audit Program (MDSAP) as a Full Member

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MedTech Europe and COCIR call for the European Union (EU) to seek full membership in the Medical Device Single Audit Program by becoming a member of the MDSAP Regulatory Authority Council ('full member') and to enable recognition of MDSAP certificates for the purpose of CE marking for medical devices and in vitro diagnostic medical devices.

Full membership will provide three key benefits:

1. *Reinforce the EU's leadership in international medical device standards by enhanced global regulatory harmonisation.*
2. *Reduce regulatory complexity and time to market by streamlined audits.*
3. *Reduce the administrative burden of multi-jurisdictional audits, fostering competitiveness and innovation, especially for small and medium-sized enterprises (SMEs).*

These benefits will ensure faster patient access to medical technologies, strengthen the EU's regulatory framework, and bolster the competitiveness of European medical device companies in global markets. In light of this, the EU should seek to become a full member of MDSAP in a timely manner. In addition, given the ongoing targeted evaluation of the EU MDR and IVDR[1]*, the EU should leverage this opportunity to enable recognition of MDSAP certificates for the purpose of CE marking.*

Launched initially in 2014 as a pilot and made fully operational by 2017, the MDSAP programme has proven to increase regulatory efficiency and collaboration. Considering the numerous benefits of MDSAP, the current level of the programme's maturity, and the fact that MDSAP audits combined with ISO 13485:2016 and MDR/IVDR audits are a reality, it would be opportune for the EU to facilitate leveraging of MDSAP certificates for CE marking purposes. To this end, the EU should also seek a full MDSAP membership of the MDSAP Regulatory Authority Council (RAC).

The EU's full membership in the MDSAP would offer significant advantages to diverse stakeholders, ultimately contributing to faster patient access to innovative medical technologies in Europe:

Benefits for patients. The streamlined audit process and more efficient reviews would expedite the time it takes for medical technologies to reach the EU market. This would help incentivising manufacturers to deliver their medical technologies to Europe. Patients in the EU would benefit from quicker access to medical technologies that improve health outcomes and standard of medical care.

Benefits for the EU. By joining MDSAP, the EU would support the goals included in the European MDR and IVDR: "*to promote the global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade*"[2]. Full membership in MDSAP would reinforce the EU's leadership in global regulatory harmonisation and convergence initiatives for medical technologies. Currently, the EU is not recognised as a jurisdiction of reference for certain regulatory reliance pathways, such as Brazil's ANVISA

[1] MDR – Medical Device Regulation - Regulation (EU) 2017/745. IVDR – *in vitro* diagnostic Medical Device Regulation - Regulation (EU) 2017/746.
[2] Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), recital (5)

Instrução Normativa 290/2024 reliance framework[3], because it is not a full MDSAP member. By becoming a full member, the EU would reinforce its standing as a reference jurisdiction and facilitate greater recognition and reliance on CE marking. This would reinforce the trust in the CE marking system and support the competitiveness of EU companies in the global market.

Benefits for EU Member States. EU Member States would be positioned as part of the global regulatory infrastructure, enhancing shared regulatory science, knowledge and relationships. These key relationships reduce duplication of regulatory efforts and enable international resources to be channelled to areas of need. Further, a unified approach to audits and compliance can lead to a more consistent enforcement of regulatory standards across Member States and globally. This can improve the overall compliance landscape while ensuring that all medical technologies meet stringent safety and performance requirements. In addition, Member States would see economic benefits from a more streamlined regulatory process, which would strengthen the attractiveness of the EU market, driving regional economic growth, competitiveness, and access to innovation. To date, 21% of the participating MDSAP facilities are located in the EU, representing 25 of the 27 EU Member States[4]. This number would likely increase with EU full membership of MDSAP.

Benefits for Notified Bodies (NBs). Notified bodies in the EU would benefit from conducting a single quality management system (QMS) audit that satisfies the QMS requirements under the EU MDR/IVDR and other leading regulatory jurisdictions. This streamlined approach reduces the duplication of efforts and administrative burden associated with multiple separate audits. With the reduced redundancy in audits, NBs can better allocate their resources, reduce costs and increase predictability, leading to more efficient use of auditors. A recent industry survey indicates that 13 of the 15 MDSAP Auditing Organisations (AOs) are EU NBs[5] and that AOs are already running combined audits for MDSAP and EU MDR/IVDR, lending insight into the potential efficiencies that could be gained by the EU fully and officially joining the MDSAP programme. With the streamlined audit process and broader market recognition if the EU were to join the programme, the number of manufacturers seeking MDSAP certification is expected to increase, providing NBs with significant growth opportunities in their client base.

Benefits for the SMEs. Approximately 90% of Europe's 37,000 medical technologies companies are SMEs[6], who often face significant challenges navigating complex and varied regulatory environment. The EU joining MDSAP as a full member would support its vibrant industrial base by providing these companies with the option to undergo a single and comprehensive quality management system audit that meets the requirements of participating countries to where they wish to expand their market. This includes the five Full Members, four Official Observers and seven Affiliate Member jurisdictions, as well as multiple additional jurisdictions that unilaterally recognise MDSAP. This option would reduce the time, cost, and administrative burden required by SMEs to access international markets, fostering growth and innovation within the EU medical device sector in a self-reinforcing loop.

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[3] https://www.in.gov.br/web/dou/-/instrucao-normativa-in-n-290-de-4-de-abril-de-2024-552512770 (last retrieved on 27 January 2025)
[4] Industry data.
[5] Note: in some cases it is the parent company located in another jurisdiction (e.g., the United States) that holds the MDSAP AOs qualification.
[6] MedTech Europe Facts & Figures 2024: https://www.medtecheurope.org/wp-content/uploads/2024/07/medtech-europes-facts-figures-2024.pdf (last retrieved on 27 January 2025)

Benefits for the industry. The European medical technology market is estimated at roughly €160 billion in 2023 – it is the second largest market after the US[7]. EU's full membership in the MDSAP programme and the ability to fully benefit from it for the purpose of CE marking is essential for the world's second largest manufacturing base. A future framework in which the EU requirements are included as an opt-in part of the MDSAP audit programme would cut costs[8] significantly by consolidating audits and reducing complexity and operational overhead for regulatory reviews, while also accelerating time-to-market for new products by eliminating redundant regulatory steps. Enhanced market access and a broader geographic reach would strengthen the global competitiveness of EU-based companies, allowing them to focus more resources e.g., on innovation. Additionally, harmonising audit standards would provide greater consistency and predictability across regions, with improved audit quality promoting patient safety and regulatory transparency. Last, MDSAP will also help companies to stay ahead of evolving regulatory requirements and being prepared for future changes in the regulatory landscape.

In conclusion, joining MDSAP as a full member would be a strategic decision, aligning the EU with a global initiative that prioritises high standards, patient safety, and innovation in the medical technology industry. It is time for the EU to take this strategic step, ensuring that European patients, industry, and regulators all benefit from a more streamlined, efficient, and globally recognised regulatory framework.

Background

The Medical Device Single Audit Program (MDSAP) is a global initiative designed to harmonise regulatory approaches as it allows an MDSAP recognised Auditing Organization to conduct a single regulatory audit of a medical device manufacturer's quality management system (QMS) that satisfies the relevant requirements of the regulatory authorities participating in the program. International partners that are currently participating in the MDSAP as Full Members are Australia's Therapeutic Goods Administration (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA, Health Regulatory Agency), Health Canada, Japan's Ministry of Health, Labour and Welfare/ Pharmaceuticals and Medical Devices Agency (MHLW/PMDA), and U.S. Food and Drug Administration (FDA). The European Union (EU) is currently an Official Observer.

[7] *Ibid.*

[8] A recent study run by the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG) indicates that the costs to transition to EU MDR/IVDR are the first reason for manufacturers to discontinue devices for the EU market. Reference: https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en (last retrieved on 27 January 2025)

About us

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. https://www.medtecheurope.org/

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 also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (https://www.globalditta.org/). https://www.cocir.org/

For more information, please contact:

Diana Kanecka, Director International Affairs (MedTech Europe): d.kanecka@medtecheurope.org
Alessia Gramuglia, Technical & Regulatory Affairs Senior Manager (COCIR): gramuglia@cocir.org