EU Health Commissioner comments on the MDR evaluation

Important signal for medical technology

During MEDICA, the leading trade fair for medical technology and healthcare, which took place in Düsseldorf in mid-November 2025, EU Health Commissioner Olivér Várhelyi emphasised the importance of Europe as a location for medical devices.

SPECTARIS, the German industry association representing optics, photonics, analytical and medical technology and more than 400 predominantly medium-sized companies, together with Messe Düsseldorf, had invited participants to a CEO roundtable. Around 5,300 exhibitors from 70 countries presented new trends and developments in the sector at MEDICA.

A particular highlight of the event was the participation of Olivér Várhelyi, who discussed the ongoing evaluation of the European Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR) with representatives of European medical technology companies. As one of the key drivers shaping the future of the MDR and IVDR within the European Commission, Várhelyi's attendance at the CEO roundtable sent a strong message to the industry.

Europe as a key location

The Commissioner pointed out that medical technology remains a strategic future sector and that Europe must continue to be a place where medical devices are developed, tested and approved. The industry regarded his clear statements as an important signal.

"The Commissioner's commitment to securing Europe as a strong innovation hub is a decisive step in the right direction," said SPECTARIS Managing Director Jörg Mayer. "For medium-sized companies, reliability and predictable regulatory processes are essential."

At the same time, Várhelyi acknowledged the long-standing issues that have burdened the sector: excessive bureaucracy, rising costs and ongoing regulatory uncertainty. The European Commission has announced its intention to present concrete short- and medium-term reform measures by the end of the year, with the aim of providing tangible relief for companies.

Alexey Shiryaev, President of Team NB representing the notified bodies, emphasised the importance of additional efficiencies within the system. These could be achieved, for example, through digital processes or early, structured dialogue between manufacturers and notified bodies to help avoid delays and to deploy the resources of notified bodies more effectively.

SPECTARIS made it clear during the discussions that, despite the positive signals, the pressure to act remains high. "The Commissioner's statements are an important sign, but the burden factors for the medical technology industry are still considerable," Mayer continued. "We need tangible and rapid relief so that innovations can reach patients more quickly again and Europe does not lose its competitiveness."

According to a SPECTARIS press release, the medical technology sector, i. e., the manufacturers of health and medical devices (including micro-enterprises) had more than 210,000 employees in Germany in 2024, generating gross added value of €38.3 billion, including spillover effects, according to the Health Economic Accounts (GGR) of the WifOR Institute. Economic statistics show that, in 2024, there were 1,508 medical-technology manufacturers in Germany with over 20 employees, generating total revenues of €41.4 billion (€60 billion including micro-enterprises).

Sixty-eight per cent of medical technology revenues come from international business. Around nine per cent of turnover is invested in research and development. Ninety-three per cent of companies are small and medium-sized enterprises.

Source: SPECTARIS press release