HPO.TECH Hyperbaric Chambers Manufacturer Completes the EU MDR Transition early

The company moved its hyperbaric chambers from EU MDD to the Medical Device Regulation (EU 2017/745), the framework now governing medical devices on the market.

HPO.TECH hyperbaric chamber systems, now certified under the EU Medical Device Regulation (EU 2017/745).

ISTANBUL, TURKEY, August 13, 2026 /EINPresswire.com/ -- HPO.TECH announced today that it has completed the transition of its hyperbaric chamber systems from the EU Medical Device Directive (MDD, 93/42/EEC) to the EU Medical Device Regulation (MDR 2017/745), becoming an early dedicated hyperbaric chamber manufacturer to do so.

MDR replaced the MDD across the European Union with a more demanding set of rules for how medical devices are evaluated, documented, and monitored in use. Where the older directive largely certified a device at the point of market entry, MDR requires manufacturers to hold stronger clinical evidence for a device's intended purpose, to assign unique identifiers that make every unit traceable through the EUDAMED database, and to run continuous post-market surveillance for as long as the device remains in clinical use.

The transition has been one of the harder passages in recent European medtech. To keep devices from dropping off the market, EU lawmakers extended the deadlines for legacy MDD certificates to 2027 and 2028, and many manufacturers are still working through that runway. HPO.TECH completing the move now, ahead of others in the hyperbaric field, indicates that its systems already met the regulation's requirements rather than relying on the extra time.

"MDR does not reward marketing. It rewards documentation," said Tolga Kabak, Chief Technology Officer and co-founder of HPO.TECH. "Meeting it meant proving, unit by unit, that our chambers do what we say they do, and that we can keep proving it for the life of the product.

That is the standard we set out to build to. Getting there this fast tells us we were already engineering the right way."

For clinicians and institutions, MDR certification also simplifies things. A chamber that meets the regulation can be placed on the market across all EU member states under a single framework, and procurement teams can assess it against the current European standard. For HPO.TECH systems already installed across Europe, it means the chambers in daily clinical use are certified to the framework that now defines the market. Certification confirms that a device meets EU requirements for safety, quality, and performance for its intended use.

The MDR transition sits within HPO.TECH's wider certification set, which includes ISO 13485 for medical-device quality management, the Pressure Equipment Directive (PED 2014/68/EU), ASME PVHO certification for pressure vessels for human occupancy, and UKCA marking for the United Kingdom.

About HPO.TECH
Founded in 2020 in Istanbul, HPO.TECH (www.hpotech.com) designs and manufactures hyperbaric, hypobaric, and multibaric chamber systems for clinical, research, performance, and wellness applications. The company is among the most certified hyperbaric manufacturers in the world, holding clearances at regional and international levels, including EU MDR, PED 2014/68/EU, UKCA, ASME PVHO, ASME U-Stamp, ISO 13485, SFDA, UAE MOH+EDE, Medsafe New Zealand, Thai FDA, GHANA FDA, and ISO 9001. Moreover, the company is in the process of obtaining USA FDA, Philippines FDA, Vietnam DMEC, Hong Kong MDACS, Mexico COFEPRIS, Singapore HSA, Taiwan FDA, and Japan PMDA.

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