Infinium Medical announces EU MDR Certification for the OMNI Series and CLEO Patient Monitors

The devices had previous clearance under the now superseded Medical Device Directive. and now have updated certification under rules set forth with EU MDR.

Infinium EU MDR & CE Award

LARGO, FL, UNITED STATES, March 5, 2025 /EINPresswire.com/ -- Infinium Medical, Inc., a US Manufacturer of medical devices, is proud to announce receipt of the European Union Medical Device Regulation (EU MDR) Certification for OMNI Series and CLEO Patient Monitors.

The devices had been previously cleared under the now superseded Medical Device Directive (MDD) and have now successfully achieved this new certification, navigating the new, more stringent requirements set forth in the EU MDR.

> Infinium has demonstrated our proven commitment to quality and ability to meet the heightened requirements put forth by the European Union for the safety and effectiveness of medical devices"
>
> *Nick Wilkens*

"This transition has been a challenge for the medical device industry, and we are extremely delighted and proud of our team for this significant achievement. In receiving this certification, Infinium has demonstrated our proven commitment to quality and ability to meet the heightened requirements put forth by the European Union for the safety and effectiveness of medical devices," said Nick Wilkins, Director of Quality Assurance and Regulatory Affairs.

With this clearance, Infinium is now able to again affix the CE mark to their line of patient monitors and continue to serve patients and partners in Europe and around the globe. Our current and upcoming USA

made patient monitors will benefit greatly from the regulatory clearance and greater commitment to quality initiatives.

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