GOING STRONG GROWING STRONGER

FOR IMMEDIATE RELEASE

Auxein Strengthens Its Leadership in Global Orthopaedic Solutions with EU-MDR Certification for Trauma Plating, Screws, and Nailing Systems

Asia's first orthopaedic implant manufacturing organization to reach this milestone for its Trauma Orthopaedic Solutions for Trauma Plating, Screws, and Nailing Systems

Certifications such as CE (EU-MDR), MDSAP, EN ISO 13485, USFDA 510K and More, Auxein Continues to Impact Global Healthcare

Delhi, India – October 18, 2024 – Auxein, a global innovator in orthopaedic and arthroscopy solutions, is proud to announce the successful achievement of the prestigious **European Union Medical Device Regulation (EU-MDR) certification 2017** issued by DNV, Norway. Auxein has made history as the first Asia's orthopaedic implant manufacturing organization to reach this milestone for its Trauma Plating, Screws & Nailing System including Tibia Plate and Screw and Femoral Nailing System. This certification strengthens Auxein's role as a leader in delivering safe, high-quality medical devices across Europe, ensuring compliance with the latest regulatory standards.

Our state-of-the-art R&D and manufacturing facility is globally recognized for adhering to the highest standards in medical device production. Certification such as **CE(EU-MDR), Medical Device Single Audit Program (MDSAP), ENISO 13485**, **USFDA 510(k),** and many, Auxein's compliance aligns us with European Union health, safety, and environmental standards.

Auxein offers a comprehensive portfolio of over 3000 orthopaedic products, designed to meet a variety of patient and clinical needs. All products are **CE-certified** and fully compliant with the European Medical Device Directive **MDD/93/42/EEC**, as amended **2007/47/EC**. Additionally, a **selected range of products** has been **US FDA 510(k) cleared**, further validating the safety and efficacy of Auxein's product offerings for global markets.

EU-MDR Certification – A Step Towards a Safer, Compliant Future

Achieving EU-MDR certification is a landmark accomplishment for Auxein, ensuring that all our orthopaedic implants—including joint arthroplasties, screws, plates, and trauma devices—meet the stringent safety and performance standards established by the European Union. This compliance positions Auxein as a key player in the European medical device market, enhancing product traceability, clinical evaluation, and patient safety.

Mr. Gaurav Luthra, Vice President Global Manufacturing and Regulatory Head at Auxein, stated, "Securing EU-MDR certification is a testament to our relentless dedication to providing the safest, most innovative orthopaedic solutions. This achievement, combined with our extensive global certifications, positions us to drive advancements in healthcare on a global scale."

Auxein's Ongoing Commitment to Innovation

With its globally certified R&D facility and an unparalleled range of orthopaedic products, Auxein remains at the forefront of medical technology. The company's dedication to **cutting-edge research** and **superior manufacturing** enables it to deliver solutions that meet the evolving needs of healthcare professionals worldwide.

About Auxein Medical: Auxein is dedicated to advancing medical technology through innovative Orthopedic and Arthroscopy solutions, committed to improving patient outcomes worldwide. We deliver excellence through cutting-edge research, superior manufacturing, and a deep understanding of healthcare needs.

Key Highlights:

- 20+ Million Patients Cared For
- 500+ Worldwide Employees
- Operations in 90+ Countries
- 3000+ Products, 200+ FDA-Approved Products

For more information about Auxein please visit: https://www.auxein.com/
For more information about DAIS Academy, please visit: https://www.dais.academy/, https://www.youtube.com/user/Auxeinmedical

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