News Release

EOS Enhances Regulatory Compliance for Medical Device Manufacturers with Master File Solution

KRAILLING, Germany, April 29, 2025 – EOS, a global leader in additive manufacturing (AM) technologies, services and materials, today announced its latest advancement in regulatory compliance support for medical device manufacturers. The EOS Medical Device Master File provides prevalidated technical data, helping streamline the regulatory approval processes while protecting proprietary information.

Regulatory compliance in the United States requires extensive testing, documentation, and engagement with governing agencies, which can lead to significant delays. The EOS Master File allows manufacturers to submit Intellectual Property (IP) directly to medical regulators, ensuring compliance while protecting proprietary data from disclosure to customers. Additionally, the Master File serves as a reference point for multiple device manufacturers, reducing redundant regulatory steps and expediting time to market.

With more than two decades of legacy of innovation and experience in the medical device manufacturing sector, EOS has cemented its reputation as a trusted partner in the AM medical industry. The EOS M 290 metal AM platform is well regarded for its production of approved medical devices, including hip cups, tibial trays and spinal cages.

EOS Medical Device Master File: A Resource for Medical Manufacturers
The EOS Master File is designed to help expedite regulatory approval by offering a single, validated source of technical data. This reduces repetitive testing, lowers regulatory friction, and minimizes delays in market entry.

- **Prevalidated process and material data:** The Master File ensures that critical parameters have been assessed and approved
- **Faster time to market:** By referencing the EOS Master File, manufacturers can avoid redundant verification processes, significantly shortening approval timelines
- **Reduced testing:** Manufacturers do not need to generate extensive validation data themselves; they only need to demonstrate that their machines perform similarly to EOS' validated process

"At EOS, we are committed to supporting our customers throughout their regulatory journey," said Davy Orye, head of Additive Minds EMEA at EOS. "With the EOS Medical Device Master File, we aim to help manufacturers navigate complex approval processes more efficiently, leveraging years of experience in supporting customers with the medical device approval process and ensuring complete confidence in compliance."

About EOS
EOS provides responsible manufacturing solutions via industrial 3D printing technologies to organizations around the world. Since 1989, EOS has shaped the future of manufacturing by enabling its customers to innovate and differentiate through expert guidance, technology and services, leveraging its end-to-end additive manufacturing (AM) industry partnerships. From strategy to education to production, EOS is the leading global partner for both metal and polymer AM solutions, accelerating time-to-market for its customers through high-quality production efficiencies and sustainable solutions.

Graphic material › EOS Press Center

EOS Contact
Jenna Phillips
Marketing Communications Specialist
+1 248.231.8089
Jenna.Phillips@eos-na.com