Synopsys Launches Simpleware ScanIP Medical with CE Marking and FDA 510(k) Clearance

Regulatory Certification Strengthens Inroads to Medical Simulation and Pre-surgical Planning Markets

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Highlights:

- Simpleware ScanIP Medical obtains CE marking in EEA
- Simpleware ScanIP Medical is FDA 510(k) cleared in the United States, and is developed using an ISO 13485:2016 quality management system

Synopsys, Inc. (Nasdaq: SNPS) today announced the launch of Simpleware™ ScanIP Medical after obtaining CE marking as a medical device. The CE marking strengthens Synopsys' offerings and provides medical device design and patient-specific analysis companies in the European Economic Area (EEA) with a robust tool for creating models from 3D imaging data. Simpleware ScanIP Medical is also FDA 510(k) cleared in the United States, and is developed using an ISO 13485:2016 quality management system.

Simpleware ScanIP Medical is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner, such as a computerized tomography (CT) scanner or a magnetic resonance imaging (MRI) scanner to an output file. The software is also intended as pre-operative software for simulating/evaluating surgical treatment options.

"ScanIP Medical receiving CE marking and FDA (510K) clearance is an important landmark," said Johann Henckel, orthopaedic surgeon at University College London and the Royal National Orthopaedic Hospital. "Having these certifications means that we can use the software for clinical applications like pre-surgical planning. This helps us incorporate ScanIP into vital areas of patient-specific implant design and simulation."

Simpleware software enables the conversion of 3D scan data into high-quality computer models used for engineering design and simulation. The Simpleware products address a wide range of product design and data analysis applications in the life sciences, consumer products, aerospace, automotive, defence, oil, and gas industries. For more information, visit https://www.synopsys.com/simpleware.html.

"ScanIP Medical, together with CE marking and FDA 510(k) clearance, shows great potential for expanding Synopsys' role in software applications for the medical simulation and pre-surgical planning market across the United States and Europe," said Terry Ma, vice president of engineering for TCAD at Synopsys. "Together with ISO certification, it further enhances Synopsys' ability to provide high-quality medical software that can consistently meet customer needs and applicable regulatory requirements."

About Synopsys

Synopsys, Inc. (Nasdaq: SNPS) is the Silicon to Software™ partner for innovative companies developing the electronic products and software applications we rely on every day. As the world's 15th largest software company, Synopsys has a long history of being a global leader in electronic design automation (EDA) and semiconductor IP and is also growing its leadership in software security and quality solutions. Whether you're a system-on-chip (SoC) designer creating advanced semiconductors, or a software developer writing applications that require the highest security and quality, Synopsys has the solutions needed to deliver innovative, high-quality, secure products. Learn more at www.synopsys.com.

Editorial Contact:
James Watts
Synopsys, Inc.
650-584-1625
jwatts@synopsys.com

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