

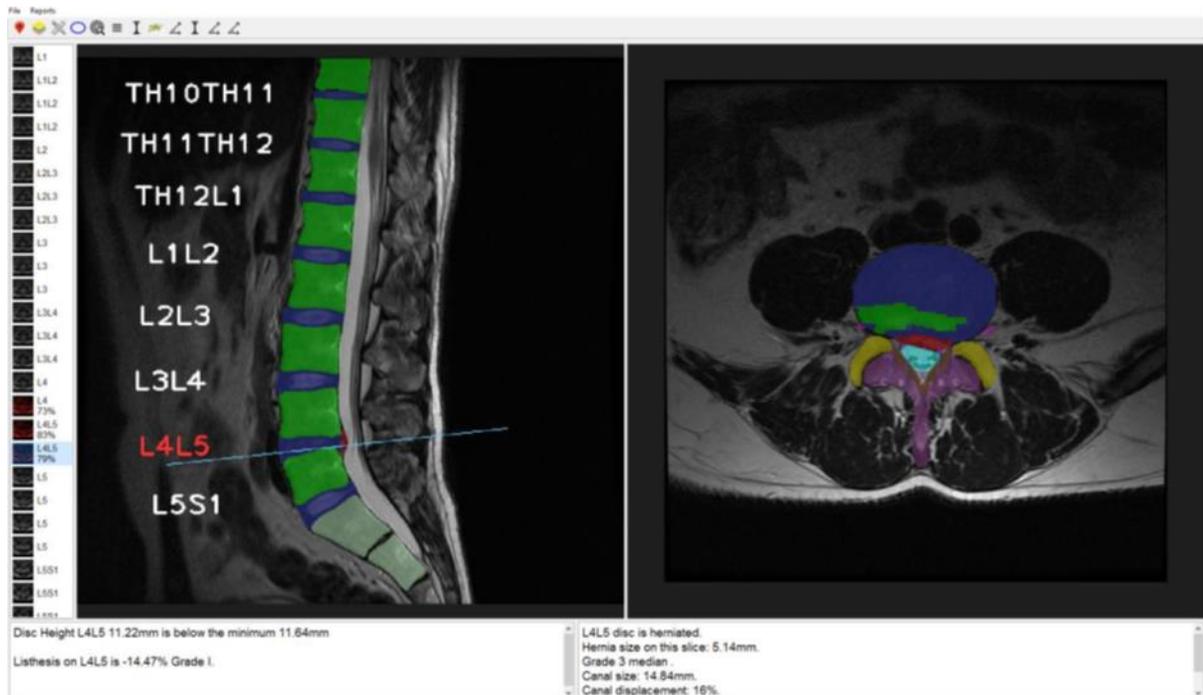
Varna, 27 January — Smart Soft Ltd, developer of automated MRI lumbar spine assistant system, today announced that the company has received ISO 13485 certification under KIWA. This certification indicates that the company's Quality Management System meets the regulatory requirements specific to the medical device industry.

The International Organization for Standardization (ISO) is the world's largest developer and publisher of international standards for the implementation of quality management systems. The ISO 13485 Quality Management Standard for Medical Devices represents the requirements for a comprehensive management system for the design and manufacture of medical devices.

Smart Soft's ISO 13485:2016 certification scope includes: Design, development, marketing and sales of medical software for radiology, neurology, orthopedics and surgery departments

This ISO 13485:2016 scope indicates that Smart Soft has established the Quality Management System that is an important milestone achievement towards CE Mark and to meet customer and international regulatory expectations. This ISO 13485 certification and scope verifies the Quality Management System designed to ensure the highest quality product development and manufacture of CoLumbo software.

The ISO 13485:2016 certification is an internationally recognized standard for the medical device industry.



### About Smart Soft Ltd

Smart Soft Ltd develops innovative software system for processing, analysis and diagnostic of lumbar spine MRI images. The system is using convolutional neural networks and unique proprietary algorithm. It performs fully automated tissue segmentation, performs key measurements and pathology detection, and creates a draft report; the application is aimed to reduce errors of omission and time needed to record the findings. More information is available on [www.smart-soft.net/products/columbo/index.htm](http://www.smart-soft.net/products/columbo/index.htm)

Commitment to quality is central to the company's mission. Achieving ISO 13485:2016 certification demonstrates that Smart Soft Ltd has successfully implemented a quality management system that conforms to the world-wide standard for medical device and validates the team's capabilities and maturity in establishing processes to develop and manufacture diagnostic products for medical use. This certificated is a testimony to the high level of performance and quality expected during development, manufacturing and sales of the company product.

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