

# DIAGNOS Successfully Completes ISO 13485 / MDSAP Audit

written by Raj Shah | January 21, 2021

January 21, 2021 ([Source](#)) – Diagnos Inc. (“DIAGNOS”, the “Corporation” or “we”) (TSX Venture: ADK) (OTCQB: DGNOF) a leader in early detection of critical health issues through the use of its FLAIRE platform based on Artificial Intelligence (AI), announces today that its quality management system continues to comply with the applicable regulatory requirements for medical devices.

As part of the requirements for the commercialization of our flagship product CARA from Health Canada and the Food and Drug Agency in the US (FDA), DIAGNOS must undergo thorough statutory annual quality compliance audits under the Medical Device Single Audit Program (MDSAP). MDSAP is a comprehensive approach to quality management systems auditing among countries devoted to enhance the safety of medical devices.

“I would like to take this opportunity to thank each of our employees for their hard work and commitment to the quality of our products. Our clients expect our healthcare solutions to perform in compliance with the highest quality standards, while being safe, and DIAGNOS is able to meet their expectations”, said **Mr. André Larente, President of DIAGNOS.**

## About DIAGNOS

DIAGNOS is a publicly-traded Canadian corporation with a mission of early detection of critical health issues through the use of its Artificial Intelligence (“AI”) tool CARA (Computer Assisted Retina Analysis). CARA is a tele-ophthalmology platform that integrates with existing equipment (hardware and software) and processes at the point of care. CARA’s Artificial Intelligence

image enhancement algorithms make standard retinal images sharper, clearer and easier to read. CARA is accessible securely over the internet, and is compatible with all recognized image formats and brands of fundus cameras, and is EMR compatible. CARA is a cost-effective tool for screening large numbers of patients in real-time. CARA complies with local regulations, is FDA cleared for commercialization in the United States of America, is Health Canada licensed for commercialization in Canada, licensed by the Saudi FDA, COFEPRIS in Mexico and is CE marking compliant in Europe.

Additional information is available at [www.diagnos.com](http://www.diagnos.com) and [www.sedar.com](http://www.sedar.com).

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