DIAGNOS Successfully Completes ISO 13485 / MDSAP Audit and receives its certification to move forward with FDA and Health Canada

written by Raj Shah | August 20, 2024

August 20, 2024 ([Source](#)) – Diagnos Inc. ("DIAGNOS" or the "Corporation") (TSX Venture: ADK) (OTCQB: DGNOF) a leader in early detection of critical health issues through the use of its FL*AI*RE platform based on Artificial Intelligence (*AI*), announces today that its quality management system fully complies with ISO 13485 standard and applicable regulatory requirements for medical devices.

As part of the requirements for the commercialization of our flagship product CARA, DIAGNOS must undergo thorough statutory 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 our employees for their hard work in this important process. Our clients expect our healthcare solutions to perform in compliance with the highest quality standards and DIAGNOS is able to meet their expectations. Without this certification we are not allowed to sell our solutions worldwide. This new certification also covers all new AI based regulatory requirements that have been approved by multiple governments including: Canada, USA and European countries," said **Mr. Yves-Stephane Couture, Chief Operating**

Officer of DIAGNOS.

"This huge achievement from our team comes at a time where Artificial Intelligence is growing and we want to be the leader in our field. DIAGNOS has reached an inflection point in its sales growth going from a one test company for diabetics to a company providing a suite of tests thereby accelerating profitability and patient satisfaction. A report from Precedence Research said that the global artificial intelligence (AI) in the healthcare Market size, which was USD 19.27 billion in 2023 is estimated at 26.69 billion in 2024 and is anticipated to reach around USD 613.81 billion by 2034, expanding at a CAGR of 36.83% from 2024 to 2034," said **Mr. André Larente, President of DIAGNOS**.

DIAGNOS is currently in the process of obtaining regulatory licences in Canada (Health Canada) and in the USA (US-FDA) for four additional modules to assist health care professionals in identifying generally abnormal through Optical Coherence Tomography retinal images and in the grading of Fundus images to detect signs of Retinopathy for general public adult, Age-Related Macular Degeneration, Diabetic Retinopathy and Hypertensive Retinopathy. DIAGNOS is also working on additional diseases through the use of the retina imaging. More information about these modules can be found in the April 16, 2024 press release on the subject.

About DIAGNOS
DIAGNOS is a publicly traded Canadian corporation dedicated to early detection of critical health problems based on its FLAIRE Artificial Intelligence (AI) platform. FLAIRE allows for quick modifying and developing of applications such as CARA (Computer Assisted Retina Analysis). CARA's image enhancement algorithms provide sharper, clearer and easier-to-analyze retinal images. CARA is a cost-effective tool for real-time screening of large

volumes of patients.

Additional information is available at www.diagnos.ca and www.sedarplus.com.

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