Validated for Global Scale: DIAGNOS Passes Annual MDSAP Audit, Solidifying the Pathway to Approvals with Health Canada & FDA

written by Raj Shah | October 8, 2025

October 8, 2025 (Source) – DIAGNOS Inc. ("DIAGNOS" or the "Corporation") (TSX Venture: ADK, OTCQB: DGNOF, FWB: 4D4A), a pioneer in early detection of critical health issues using advanced technology based on Artificial Intelligence (*AI*), announces the successful completion of the annual surveillance external quality compliance audit under the Medical Device Single Audit Program (MDSAP) performed in June of this year.

The audit confirmed **full compliance** across all operational and development processes, with **no single non-conformities** raised. This demonstrates DIAGNOS' strong commitment to quality, regulatory excellence, and continuous improvement.

Following this review, Intertek reissued the Company's certification with an updated scope reflecting DIAGNOS' **Software-as-a-Service (SaaS)** deployment model for its AI-assisted medical image-analysis platform. This evolution aligns the Company's quality framework with its expanding **global strategy**.

Yves-Stéphane Couture, COO of DIAGNOS, stated:

"This renewed certification demonstrates our readiness to scale our SaaS-based AI platform globally while maintaining the

rigorous quality and compliance standards required by regulators. It's a strong signal to our partners and licensing bodies – DIAGNOS is **accelerating the path to approvals** with **Health Canada, the FDA, and the SFDA**. Our cloud deployment model allows us to deliver innovation faster, securely, and with measurable impact for healthcare providers."

"I would like to sincerely thank our Quality, Conformity, & Regulatory Affairs Specialist, Mr. Eric Boucher, and all DIAGNOS employees for their dedication throughout this process. Our clients expect our healthcare solutions to perform in compliance with the highest standards – and DIAGNOS continues to meet and exceed those expectations."

This successful audit strengthens DIAGNOS' position in ongoing regulatory submissions and supports its core mission which is centered on supporting Health Care Professionals (HCP) in **early detection of critical health issues using Artificial Intelligence (AI)**.

About MDSAP
MDSAP is a regulatory audit program of a medical device manufacturer's Quality management system. The program aims to reduce the number of audits a manufacturer undergoes by allowing a single annual audit to meet the regulatory needs of participating countries, which include assessing compliance with ISO 13485 and country-specific regulations.

About ISO 13485
ISO 13485 is the harmonized standard for Quality management system (QMS) in the medical device manufacturing industry. It outlines the requirements needed for organizations to establish a QMS that demonstrates the capability to consistently and safely deliver medical devices, and related services, as well as meeting customer and regulatory requirements.

About DIAGNOS

DIAGNOS is a publicly traded Canadian corporation dedicated to early detection of critical eye-related health problems. By leveraging Artificial Intelligence, DIAGNOS aims to provide more information to healthcare clinicians to enhance diagnostic accuracy, streamline workflows, and improve patient outcomes on a global scale.

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

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