



RNS Number : 1824Y  
EKF Diagnostics Holdings PLC  
03 May 2023

**EKF Diagnostics Holdings plc**  
("EKF" or the "Company")

**Successful quality management audits for enzyme fermentation sites**

*Largest fermenter on track for complete validation by end of Q3 2023*  
*Other new Life Sciences capacity on track for operational activity from this summer*

EKF Diagnostics Holdings plc (AIM: EKF), the AIM-listed global diagnostics business, announces that its Life Sciences division's enzyme fermentation sites in Indiana have successfully completed their ISO 9001: 2015 and ISO 13485: 2016 quality management audits. This is the first such audit of the South Bend facility and is a testament to the investment and effort to date that has gone into preparing this new site to be operational. The Company remains on track to have all new fermentation capacity in South Bend installed and validated towards the end of Q3 2023.

Once installation is completed the Life Sciences division we will have installed 65L, 300L, 1,500L, 3,000L and 14,500L fermentation units at its South Bend facility, complementing the existing capacity provided by the division's existing 10L (x2), 125L and 1,600L fermentation units at the Elkhart facility. Whilst the largest fermenter (14,500L) will be installed and validated in Q3 2023, the new other fermenters are on track to be operational and revenue generating over the summer.

ISO 9001:2015 Quality Management Certification is an International Standard for Quality Management Systems, and demonstrates that an organisation is customer-focused and committed to delivering high quality services. ISO 13485:2016 is a standard for Quality Management Systems that specifically relate to products and services with a health purpose, and shows that an organisation provides medical devices and related services that consistently meet customer and applicable regulatory requirements.

The three-day audit was based on a series of successful fermentation validation runs at the South Bend facility using new fermenters and a full review of the division's

Quality Management Systems.

**Julian Baines, Executive Chair, commented:** *"We're very pleased that the audit planned for April has completed successfully and that our facilities continue to operate to the highest industry standards. This business has manufactured enzymes and biomolecules from bacterial fermentations for the last 40 years and our customers have always welcomed our unwavering commitment to providing the highest quality service. Developing our quality assurance as we increase our capacity is key to the successful scale up of these operations and I'm delighted that we remain on track."*

**EKF Diagnostics Holdings plc**

Julian Baines, Executive Chair / Marc Davies, CFO

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**About EKF Diagnostics Holdings plc** ([www.ekfdiagnostics.com](http://www.ekfdiagnostics.com))

EKF is an AIM-listed global diagnostics business focussed on:

- **Point-of-Care** analysers in the key areas of Hematology and Diabetes, as well as Central Laboratory products including clinical chemistry reagents, analysers and centrifuges
- **Life Sciences** services provide specialist manufacture of enzymes and custom products for use in diagnostic food and industrial applications, as well as other higher value Contract Manufacturing services

EKF has headquarters in Penarth (near Cardiff) and operates five manufacturing sites across the US and Germany, selling into over 120 countries world-wide.

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