PRESS RELEASE

# EDT Announces ISO 13485 Compliance

November 2020

ISO 13485:2016 is an internationally recognized quality standard specific to the medical device industry and we are proud to announce that as of September 14th, 2020 we have been certified as compliant by SGS. This establishes Emerging Display Technologies Corporation as a trusted partner in the medical device industry providing customers with higher-consistency, lower-risk, more stable products, and comprehensive and specialized services in compliance with the ISO 13485 standard.

The primary objective of ISO 13485 is to facilitate harmonized medical device regulatory requirements for quality management systems. ISO 13485 is a standalone standard. It is largely based on the structure of ISO 9001, but includes some special requirements for medical devices such as risk analysis and traceability.

This medical certification will complement an extensive range of other industrial standards that our company has achieved and will continue to maintain as a loyal service to our market and customers.

We look forward to working with the many companies that require ISO 13485 certification as a condition of doing business. While not explicitly required by law, ISO 13485 is aligned with many global regulations. These include CE marking of medical devices under European Directives as well as U.S. Food and Drug Administration (FDA) quality and safety requirements that medical device manufacturers must follow.

CEO Pauli Wang
Emerging Display Technologies Corp.

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