Zentek Receives ISO 13485:2016 Certification

written by Raj Shah | May 18, 2023

May 18, 2023 (Source) – **Zentek Ltd.** (“**Zentek**” or the “**Company**“) (Nasdaq:ZTEK)(TSXV:ZEN), a graphene technology development and commercialization company has been granted ISO 13485:2016 Quality Management System (QMS) certification standard by British Standards Institution (BSI). The company has also received Medical Device Single Audit Program (MDSAP) certificate # 777967. These certifications validate Zentek’s robust QMS that can handle all regulated products and demonstrate safety, reliability, and quality.

ISO 13485:2016 is an internationally recognized quality standard for the medical device industry that supports the quality of medical device design, development, and production. MDSAP is currently utilized by Canada, the United States, Japan, Australia, and Brazil.

Under the supervision of Vivian Martin, Director of Global Regulatory Affairs, Zentek developed and implemented a state-of-the-art QMS system specific to Zentek. The QMS was developed in-house and is wholly owned by Zentek. This QMS not only combines the requirements of ISO 13485:2016 and MDSAP, but also Medical Device Regulations (MDR) for the European market. The company has been audited for all 3 QMS systems and expects to receive certification for MDR once a final review of the audit report has been completed. The company will report when this certification is received. These certifications will facilitate new approvals for ZenGUARD™ surgical masks and other medical devices in other global markets. The company will report when it receives such approvals in new countries.

“We are very proud of the hard work by our Quality and Regulatory team to successfully complete the rigorous process to become an ISO 13485:2016 certified company. This reflects the dedication Zentek has to Standard Operating Procedure-driven processes and to continuous improvement, along with our commitment to safety and consistent quality products,” said Greg Fenton, CEO of Zentek. “Our partners, suppliers and customers can be confident that Zentek products are manufactured with stringent quality control and SOP-driven processes.”

About Zentek

Zentek is an ISO 13485:2016 certified graphene technology company focused on the research, development, and commercialization of graphene-based novel products to give its commercial partners a competitive advantage by making their products better, safer, and greener.

Zentek’s patented ZenGUARD™ coating is shown to have 99-per-cent anti-microbial activity and to significantly increase the bacterial and viral filtration efficiency of both surgical masks and HVAC systems. Zentek’s ZenGUARD™ production facility is located in Guelph, Ont. Zentek’s second technology is the patent pending ZenARMOR™ platform focused on corrosion protection applications.

For further information:

Mitch Swergold
Tel: (917) 930-8723
Email: mswergold@zentek.com

To find out more about Zentek, please visit our website at www.Zentek.com. A copy of this news release and all material documents in respect of the Company may be obtained on Zentek’s SEDAR profile at http://www.sedar.com/.

Forward-Looking Statements

This news release contains forward-looking statements. Since forward-looking statements address future events and conditions, by their very nature they involve inherent risks and uncertainties. Although Zentek believes that the assumptions and factors used in preparing the forward-looking information in this news release are reasonable, undue reliance should not be placed on such information, which only applies as of the date of this news release, and no assurance can be given that such events will occur in the disclosed time frames or at all. Zentek disclaims any intention or obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, other than as required by law.

Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.

SOURCE: Zentek Ltd.