Press release
Lund, Sweden, 21 November 2022
This is a translation of the Swedish press release published 2022-11-21

Milestone achieved by Neola Medical - approved certification of quality management system according to ISO 13485

Neola Medical AB (publ) today announces that the company has received certification of the quality management system according to ISO 13485, which is a critical step towards achieving CE marking and granted marketing authorization by FDA in the United States. An important milestone in the company's commercialization plan has thus been achieved.

Neola Medical has undergone an extensive review process of its quality management system with an approved result, which means that the company has been certified according to ISO 13485. The certification shows that the company has a well-reviewed and comprehensive quality management system for the development, sale, and fulfillment of regulatory market requirements of medical technology equipment. It is an important milestone in the regulatory plan and a prerequisite for achieving CE marking and granted marketing authorization by FDA in the United States. The certification is carried out by BSI Group The Netherlands B.V., a leading internationally accredited certification body.

"We continue to show that we are achieving our set milestones according to plan. A certified quality management system is a prerequisite to sell medical devices internationally, and the certification means that we now have another cornerstone in place in our commercialization plan.", says Hanna Sjöström, CEO at Neola Medical.

About BSI
BSI was founded 1901 in Great Britain and was the world's first national certification body. Today, BSI is one of the leading suppliers of standards-related services, evaluation, and certification of management systems. BSI is a global actor present in 193 countries and working with over 12 000 committee members.

ISO 13485
ISO 13485 specifies requirements for a quality management system for companies providing medical devices and related services. The certification of the management system involves fulfillment of requirements for security, traceability, reporting to authorities, customer requirements and fulfillment of legal requirements.

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Neola Medical AB (publ) develops medical technology device for continuous monitoring of preterm born infants' lungs. Immediate detection of complications provides the possibility of early treatment and improved health care. The patented technology is based on a spectroscopic method developed at Lund University in Sweden. The company was founded in 2016 as a wholly owned subsidiary of Gasporox AB (publ) under the name GPX Medical AB. The company is listed on NASDAQ First North Growth Market (ticker: NEOLA). Read more on www.neolamedical.com. The company's Certified Adviser is FNCA Sweden AB.