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Boule Diagnostics receives US FDA warning letter

Boule Medical (a Boule Diagnostics subsidiary) has today received a warning letter from the US FDA (Food and Drug Administration). After a routine inspection at the Boule instrument manufacturing site in Sweden in May 2018, Boule Diagnostics received inspectional observations from the FDA. Boule has dedicated significant resources to addressing these observations, and have responded to the FDA with an action plan according to the timelines and implemented procedure improvements accordingly. The warning letter states that the implemented procedure improvements are not adequate and that further evidence of implementation and staff training on the new procedures, as well as retrospective review, is required.

Boule Diagnostics takes compliance with regulations very seriously, and this matter has the highest priority in the company. Boule Diagnostics will continue to dedicate required resource to this matter, and intends to fully cooperate with the FDA to resolve these issues and to fully comply with all relevant FDA regulation.

The warning letter does not cause limitations on production or sale of products.

For further information, please contact:

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About Boule Diagnostics AB (publ)

Boule Diagnostics AB is a global diagnostics company that develops, manufactures and markets instruments and consumable products for blood diagnostics. The company serves hospitals, clinics, laboratories and companies within blood diagnostics, in both human and veterinary hematology. The company operates via subsidiaries in Sweden, the USA and Mexico. The company's products are sold globally primarily through distributors, supported by Boule's own local sales and support personnel. The Boule shares are listed on Nasdaq Stockholm since 2011. www.boule.com

This information is information that Boule Diagnostics AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 19.15 CET on October 5, 2018.