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VibroSense Dynamics (publ): VibroSense Meter® II, CE-approved according to the new EU Medical Device Regulation

The VibroSense Meter® II system (VSM II) is registered to comply with the new EU Medical Device Regulation (MDR) as a class 1 Medical device. A registration is made at the Swedish Medicines Agency where VibroSense Dynamics has received the EUDAMED registration number (SRN) SE-MF-000003787. Thus, the VibroSense Meter® II system has now a CE-mark which complies with the new MDR which became mandatory within the EU since May 26, 2021.

After extensive work, VibroSense fulfills all requirements for CE marking of VibroSense Meter® II according to the MDR. This includes everything from ensuring that the instrument meets required standards for patient safety as well as safety for operating personnel, to that the instrument works according to the declared intended purpose.

- I am very pleased to inform that we have taken an important step to continue our sales of VibroSense Meter® II to our target groups working with healthcare within Diabetes and Chemotherapy Induced Peripheral Neuropathy. Potential customers and research projects can thus be given the opportunity to safely execute relevant clinical evaluation of VibroSense Meter® II, in order to decide on the purchase or licensing of the instrument, says Hans Wallin, CEO VibroSense Dynamics AB.

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About VibroSense Dynamics AB (publ)
VibroSense Dynamics AB (public) develops and markets efficient systems to support early detection and diagnosis of sensory neuropathy, i.e. disease of large nerve fibres and nerve trunks in e.g. legs and arms. The Company, founded in 2005, has been listed on Spotlight stock market since May 2015.