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SciBase MDR certification delayed two weeks.

STOCKHOLM, SWEDEN, — April 12, 2021 – SciBase Holding AB ("SciBase") [STO:SCIB], a leading developer of augmented intelligence-based solutions for skin disorders, announced today that it has today received information that the certification process under the new Medical Device Regulation (MDR 2017/745) has been slightly delayed due to resource issues at the notified body.

As there are no outstanding questions, we expect that the internal process at the notified body will be finalized by the end of April thus delaying the certification process by two weeks from our expected date. MDR is a set of mandatory legal requirements and central for all companies selling medical devices in the EU. The new regulation will come into force on the 26th of May this year.

"Unfortunately, Covid-19 and the extremely high pressure on all notified bodies from Companies has delayed our MDR certification by two weeks. This is both unexpected and highly frustrating after more than two years working on this project, but this part of the process is out of our hands. At this time we do not see a risk for further delay, but this final step lies with our notified body." says Simon Grant, CEO of SciBase.

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About SciBase and Nevisense
SciBase AB is a global medical technology company based in Stockholm, Sweden that develops unique point-of-care devices for the evaluation of skin disorders such as skin cancer and atopic dermatitis. SciBase's first product, Nevisense, helps clinicians detect melanoma, the most dangerous type of skin cancer. Further development has led to Nevisense also being used as a tool to assess the skin barrier and non-melanoma skin cancer. Nevisense is based on substantial research and has achieved excellent results in the largest clinical study ever conducted on the detection of malignant melanoma. Nevisense is CE marked in Europe, has TGA approval in Australia and an FDA approval (PMA) in the United States. SciBase technology is based Electrical Impedance Spectroscopy (EIS) combined with Artificial Intelligence (AI) algorithms that interpret the varying electrical properties of human tissue to detect malignancies and abnormalities. SciBase Holding AB is listed on First North Growth Market ("SCIB"). Further information is available at www.scibase.com.