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SciBase receives important European MDR certification

STOCKHOLM, SWEDEN, — May 10, 2021 – SciBase Holding AB ("SciBase") [STO:SCIB], a leading developer of augmented intelligence-based solutions for skin disorders, announced today that it has been granted certification under the new Medical Device Regulation (MDR).

MDR is a set of mandatory legal requirements central for all companies selling medical devices in the EU. The new regulation comes into effect on May 26th. SciBase is one of very few medical device manufacturers to have completed the MDR certification, after an intensive two year process. With the MDR Certification in place SciBase can release new products, indications and functionality such as their new Non-melanoma Skin cancer (NMSC) application.

The MDR was introduced by the European Union to establish a modernized and more robust legislative framework for medical devices. The aim is to ensure better protection of public health and patient safety by improving the quality, safety and performance of medical devices.

Until now, Medical devices have been CE-marked through the MDD (Medical Device Directive). Following various incidents such as the PIP breast implant scandal in France, the EU decided to improve safety and control by strengthening the regulation of medical devices. The result is the MDR industry regulations.

MDR tightens the control mechanisms for medical devices, including medical software and Apps and will have substantial impact on medical device manufacturers and distributors.

"Achieving MDR has been a strategically important goal for SciBase, because MDR is necessary for us to add new applications such as NMSC (Non-Melanoma Skin Cancer) to our platform – which is key to our strategy. For customers this will result in better products. For the industry this raises the bar in terms of what it takes to operate in this space. This has been a challenging project for SciBase, where parts of the process that were out of our hands didn't progress as we expected; but we made it in the end. I believe many companies will struggle to achieve certification and so we believe MDR certification will be a competitive advantage going forward. Overall, it is another milestone as we execute our strategy to provide our customers with additional clinical applications using our unique technology platform" says Simon Grant, CEO of SciBase.

This information is information that SciBase Holding 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 16.00 CET on May 10, 2021.

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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.