

Article on consequences of MDR regulation within Dermatology published in JEADV

STOCKHOLM, SWEDEN, — November 29, 2021 – SciBase Holding AB ("SciBase") [STO:SCIB], a leading developer of augmented intelligence-based solutions for skin disorders, announced today, that an article describing the consequences of the new medical device regulation (MDR) in the EU has been published in the journal "Journal of the European Academy of Dermatology and Venereology" (JEADV).

The new MDR regulation that came into force on May 26 2021 will have significant effects for the medical device industry and for clinicians, including Dermatologists. Firstly, many more products, especially software or app-based products require regulatory approval and control. This affects many products within Dermatology that previously were not regulated. There are also more stringent requirements within clinical evidence and the approval of product changes.

MDR will most likely have positive effects on the quality of devices, to the benefit of patients, but may also have effect on the availability of new and existing devices and methods. SciBase is one of very few companies in the field of dermatology that is certified according to the new more stringent MDR regulation.

"We believe this article will help the Dermatology field understand the implications of this new regulation and how it will affect their access and use of products, which in turn can affect the care they give their patients. I think this will affect the buying decisions of clinicians, and that they will be much more likely to purchase from MDR-certified companies." says Simon Grant, CEO of SciBase

The article was a collaboration between Dermatology clinicians and regulatory experts with input from SciBase and can be found at the JEADV journals homepage:

<https://onlinelibrary.wiley.com/doi/abs/10.1111/jdv.17830>

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About SciBase and Nevisense

SciBase is a global medical technology company headquartered in Stockholm, Sweden, that has developed a unique point of care platform for the non-invasive detection of skin cancer and other skin conditions.

SciBase is a pioneer within augmented intelligence, combining artificial intelligence with Electrical Impedance Spectroscopy (EIS) to provide objective information that assists dermatologists and others in clinical decision-making. SciBase's products include Nevisense and Nevisense Go and to date the platform addresses the areas of melanoma detection, non-melanoma skin cancer detection and skin barrier assessment. Nevisense is the only FDA-approved device for the detection of melanoma and the only MDR-approved technology for skin cancer detection in Europe. SciBase's technology is based on more than 20 years of academic research at the Karolinska Institute in Stockholm, Sweden. For more information please visit www.scibase.com.