

Press release September 3, 2019

Actiste – world's first unified IoT diabetes care device – has received market approval (CE mark).

Actiste®, the world's first unified diabetes care device with eSIM technology for monitoring and treating insulin-dependent diabetes, has received not only one, but two, EC certificates (CE marks) from TÜV Rheinland (Notified Body).

"This is a truly unique situation in a European regulatory context," says Brighter's CEO Henrik Norström.

The EC certifications allows the company to move forward with its ongoing market entry and sales activities in the company's primary target markets in the Middle East and Southeast Asia, and opens up for future sales in over 30 European countries, where Sweden is most imminent. The development of the Actiste device was initiated in 2015. In June, 2019, Brighter [received](#) ISO 13485 certification.

"We are very pleased with how quickly product development has progressed given the complexity of the solution. The certification of the Actiste device was the last missing piece in our flagship offering Actiste® Diabetes Management as a Service, which means that we now can intensify our marketing and sales efforts. This is a historic breakthrough for Brighter and we are now moving forward with great confidence," says Henrik Norström, CEO Brighter.

Actiste® is the world's first complete IoT-health solution for monitoring and treating insulin-dependent diabetes, bringing together all required functions in a single mobile-connected device: blood sampling, blood glucose measurement and insulin injection. The collection of and feedback on valid real life health data will facilitate optimised and personalised diabetes management and contribute to the improvement of everyday metabolic control and enable behavioural change.

In regulatory terms, it is a combination device based on the intersection between MDD and IVDD, which made the regulatory process for the device very complex.

"One can say, it is a double set of regulatory requirements that we needed to interpret and simultaneously apply to one and the same product, as well as three times as many different technical requirements as could be expected for a single purpose device.

These requirements, in their turn, cover several different fields of technological expertise: mechanics, electronics/hardware, firmware/software, radio connectivity. In terms of MDD, Actiste includes both active (related to energy source) and non-active (purely mechanical) aspects. Therefore, the technical documentation review of Actiste by our Notified Body required involvement of the experts in four different areas: IVDD, MDD Active devices, MDD Non-active devices, Medical Device Software. After the expert review, the results were additionally attested by three different certifiers.

Furthermore, combination devices lying in the intersection of several EU directives, are usually governed under one primary directive, while the other directives are recognized as secondary to the primary one, which leads to one EC certificate. However, Actiste, where aspects governed under MDD and IVDD are so deeply integrated, has received not only one, but two EC-certificates, one for MDD and one IVDD. All this makes the award of the CE marks quite extraordinary," says Henrik Norström.





Using state-of-the-art eSIM technology, the device has a global out-of-the-box connectivity, making it completely independent of other devices to share health and treatment data. Actiste reduces the number of steps for daily diabetes care by up to 67% – from 28 steps to 9 – compared to other solutions on the market. Furthermore, Brighter's patented technology enables unique logging of the actually injected doses and the possibility to track missed doses.

The Actiste device is delivered as part of a subscription service; Actiste® Diabetes Management as a Service. The service includes global connectivity, different levels of data sharing, continuous replenishment of everyday supplies directly to the home and individualized coaching to optimize and improve treatments.

“The Actiste service can provide healthcare facilities and staff with new insights regarding the patients’ everyday life and treatment adherence. When it comes to chronic diseases, it is the time between the physical check-ups that is important, but today healthcare is lacking that information, leading to inefficient processes. They need valid data forming the basis for better and more efficient treatments,” says Henrik Norström, CEO Brighter.

Addressable market

Actiste® Diabetes Management as a Service is a complete end-to-end service for people with insulin dependent diabetes. Initially, the company will focus on establishing the service in the Middle East, Sweden and Southeast Asia. According to the International Diabetes Federation (IDF), the total number of people living with diabetes will increase from 425 million to nearly 630 million over the next 20 years. The total number of insulin-requiring patients today is approximately 150–200 million people. In January 2019, Actiste was launched in the United Arab Emirates in collaboration with MOHAP (UAE Ministry of Health and Prevention), which published a [press release](#) on the initiative.

About Actiste.

Brighter's solution Actiste® handles most of the self-monitoring and treatment of insulin-treated diabetes in a single easy-to-use device. Measurement of glucose levels, insulin injections, automatic logging, and timing of all activities are performed from a single unit. Actiste is connected via an autonomous and secure mobile connection, and information can be automatically shared with selected recipients through The Benefit Loop®, Brighter's open cloud-based service where data is collected, processed and analyzed with patient consent.

Validated user-generated data, such as glucose levels or insulin doses, can be automatically transferred electronically to many different constituents. The patient selects when and how data is shared and who will have access to it. Through The Benefit Loop, different services can motivate patients with chronic illnesses to change their behavior, which can save lives, reduce relatives' concerns, and release enormous healthcare resources. <https://actiste.com/>

About Brighter AB (publ).

Brighter is a Swedish-based company that, from a unique IP portfolio, creates smart solutions for one of healthcare's biggest challenges: changing patient behavior. Chronic diseases such as diabetes are rapidly increasing, and account for an increasing share of healthcare costs globally. Brighter's Business Model and Multi-Sided Market Platform - The Benefit Loop®- is based on the fact that many special interests create value for each other. By increasing access to valid health data, Brighter creates value for all stakeholders in the care chain: patients and their close associates, healthcare providers, research institutes, the pharmaceutical industry, and society as a whole. Brighter is certified under ISO 13485. In 2019 the company won the Swecare Rising Stars Award. <https://brighter.se/>





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This information is information that Brighter 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 persons set out above, at 10:48 CET on September 3, 2019.



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