



Observe Medical receives MDR certification under the new European Medical Device Regulation

Oslo, April 1, 2022 - Observe Medical ASA ("the Company" or "Observe Medical") today announces that the Sippi® Disposable Unit has received Medical Device Regulation Certification, ensuring continued market access for the unit in Europe after 2024.

Rune Nystad, CEO of Observe Medical, commented: "The MDR Certification confirms that the Sippi® Disposable Unit is compliant with the latest requirements for medical devices in Europe. This is important as it demonstrates our commitment not only to adhere to the latest regulatory compliance but also to ensuring our clients that we deliver safe and high-quality products."

Having replaced the Medical Device Directive (MDD) process, the Medical Devices Regulation (MDR) was introduced in Europe in 2021 with the aim to improve the overall quality, safety and reliability of medical devices that are commercialized on the European market.

"This certification marks a significant milestone for Observe Medical and demonstrates the quality of the Sippi® Disposable Unit. Knowing the magnitude of medical devices that would need to move from the old regulatory system, MDD, to the new Medical Device Regulation, MDR, , Observe Medical was early to ensure the audit of it's medical devices. This certification is the result of the hard work by the dedicated team at Observe Medical, and I am proud of how far we have come to ensure regulatory compliance our medical devices , " said Jenny Wennerberg, QA/RA Director at Observe Medical.

The Sippi® system is Observe Medical's proprietary automated digital urine meter. The system has wireless connectivity and can transfer data to the patient management systems. The system also has biofilm indicator and lower the riskfor bacterial migration that can lead to urinary infections. The Sippi® system consists of two units, the disposable unit, the bag and measurment chamber, and the base unit, the digital system measuring hourly diuresis.

Observe Medical is in the process of obtaining MDR Certification for the Sippi® Base Unit, and until 2024 it is certified under MDD. This means that the complete Sippi® system can be sold and marketed in Europe.

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About Observe Medical

Observe Medical is a Nordic medtech company that develops, markets and sells innovative medtech products for the global market. The Company is committed to improving patient welfare and patient outcomes, improving clinical data accuracy and promoting positive health economics.

The Company seeks to drive growth by leveraging its expertise in sales and commercialization of its broad portfolio of medical technology products, mainly in urine measurement, anesthesiology/ICUs, surgery and wound care, in combination with targeted M&A.

The Company is headquartered in Oslo, Norway, with additional offices in Narvik, Norway and Gothenburg, Sweden, and subsidiaries in Finland and the US. In addition, Observe Medical has a direct sale organization in the Nordics and a distributor network internationally.

Further information is available at www.observemedical.com.