

Modular Medical Announces BSI Group as Trusted Body for CE Mark Clearance

- Engaged BSI Group to start the process of obtaining regulatory clearance of the MODD1, next-generation insulin pump for the European market

- Targeting Q1 2026 for expected clearance of the MODD1 in the E.U.

SAN DIEGO, CALIFORNIA / ACCESS Newswire / January 30, 2025 / Modular Medical, Inc. (NASDAQ:MODD) (“Modular Medical” or the “Company”), an insulin delivery technology company with the first FDA-cleared patch pump designed specifically to target all adult “almost-pumpers” with its user-friendly and affordable design, announced that BSI Group will serve as the notified body for the European regulatory clearance process.

Unlike the U.S. process, European Union (“E.U.”) clearance of a medical device is driven by a series of audit steps driven by a third party, known as a notified body, retained by the sponsor of the device to determine safety and efficacy, and the notified body then certifies that the CE mark standards have been met. Once the CE mark is obtained, a device can be marketed and sold in Europe and other areas that rely on the CE mark. BSI Group will serve as the notified body for Modular Medical for its CE clearance process.

“The MODD1 insulin pump is an ideal fit for the European marketplace,” stated Jeb Besser, CEO of Modular Medical. “With U.S. clearance in hand, we are focusing our regulatory efforts on the opportunity in the E.U. In Europe, pump penetration has been challenged with its high cost, considerable environmental impact and complexity of use. We believe that our combination of simplicity to learn and use and the low cost of our device, combined with its lower carbon footprint, reusable electronics and attractive form factor for the patient, will motivate more multiple daily injectors to adopt pumping.”

Modular Medical currently believes that it will obtain the CE mark during the first quarter of 2026.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are subject to risks, trends, and uncertainties that could cause actual results to be materially different from the forward-looking statements contained in this press release, including but not limited to, whether the Company can obtain the CE mark for the European market; potential market opportunities in the E.U. and other areas where the CE mark is accepted; the Company’s ability to convert patients to use its MODD1 pump; the occurrence of future events or circumstances; successful development of Modular Medical’s proprietary technologies; whether the market will accept Modular Medical’s products and

services; anticipated consumer demand for the Company's products; whether Modular Medical can successfully manufacture its products at high volumes; and general economic, industry and political conditions in the United States or internationally, as well as other risk factors and business considerations described in Modular Medical's SEC filings, including its annual report on Form 10-K. Any forward-looking statements in this press release should be evaluated in light of these important risk factors. In addition, any forward-looking statements included in this press release represent Modular Medical's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. Modular Medical assumes no obligation to update these forward-looking statements, except as required by law.

About Modular Medical

Modular Medical, Inc. (NASDAQ:MODD) is a development-stage medical device company that intends to launch the next generation of insulin delivery technology. Using its patented technologies, the company seeks to eliminate the tradeoff between complexity and efficacy, thereby making top quality insulin delivery both affordable and simple to learn. Our mission is to improve access to the highest standard of glycemic control for people with diabetes taking it beyond "superusers" and providing "diabetes care for the rest of us."

Modular Medical was founded by Paul DiPerna, a seasoned medical device professional and microfluidics engineer. Prior to founding Modular Medical, Mr. DiPerna was the founder (in 2005) of Tandem Diabetes and invented and designed its t:slim insulin pump. More information is available at <https://modular-medical.com>.

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