

Modular Medical Announces Ongoing Progress to Obtain CE Mark

Key Highlights:

- ***Pivot continues to progress toward CE Mark certification in 2026***
- ***Stage 1 ISO Audit completed with Stage 2 planned for 1H2026***

SAN DIEGO, CA / ACCESS Newswire / October 28, 2025 / Modular Medical, Inc.

(Nasdaq:MODD) (“Modular Medical” or the “Company”), a leader in innovative insulin delivery, today announced that it is continuing to progress toward CE Mark certification under the European Union Medical Device Regulation (“EU MDR 2017/745”). As part of this process, the Company is pleased to announce the successful completion of its Stage 1 ISO 13485:2016 audit, conducted by BSI, its Notified Body and Registrar.

The audit evaluated Modular Medical’s quality management system (“QMS”) for compliance with ISO 13485:2016 and alignment with EU MDR 2017/745 requirements, to confirm that the Company’s QMS is robust and well-documented, with no major nonconformances identified.

“This milestone reflects the dedication of our team and our commitment to bringing innovative, patient-friendly, insulin delivery solutions to market in Europe and beyond,” stated Jeb Besser, CEO of Modular Medical.

Completion of the Stage 1 audit paves the way for Modular Medical to advance to its Stage 2 audit in early 2026 – the final step before achieving the required ISO 13485 certification. In parallel, the Company will begin preparations for its CE technical documentation review under EU MDR 2017/745, which is anticipated to commence later in 2026. Successful completion of these steps is required for Modular Medical’s planned commercial launch in the European Union.

The Pivot insulin delivery system is not currently cleared for sale by the U.S. Food and Drug Administration or in any other market outside the U.S.

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, the Company’s ability to complete the required audits and obtain CE mark clearance; the Company’s intent to market its Pivot product in the

European Union and other international markets; the Company's ability to convert patients to use its MODD1 pump and gain market share; 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, general economic, and industry or 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. Its 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>.

All trademarks mentioned herein are the property of their respective owners.

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