FDA Clears MiniMed™ 780G System to Enable Integration with the Instinct Sensor, Made by Abbott, and Approves Use in Type 2 Diabetes

GALWAY, Ireland, Sept. 2, 2025/PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced two U.S. Food and Drug Administration (FDA) regulatory milestones that broaden the MiniMed™ 780G system portfolio: clearance of the SmartGuard™ algorithm as an interoperable automated glycemic controller (iAGC), enabling integration with the Instinct sensor, made by Abbott, for type 1 diabetes, and approval of the MiniMed™ 780G system for use in adults 18+ with insulin-requiring type 2 diabetes.

"These milestones mark an important next step in our work to bring the proven performance and outcomes of our MiniMed™ 780G automated insulin delivery system to more people living with diabetes. By enabling integration with the Instinct sensor and expanding the MiniMed™ 780G system to people with type 2 diabetes, we are advancing a smart dosing ecosystem designed to provide greater choice and flexibility, along with a more seamless experience," said Que Dallara, Executive Vice President and President of Medtronic Diabetes and CEO Designate of MiniMed. "We're excited to expand our ecosystem of solutions under one roof with service our customers can count on around the clock."

This clearance, alongside the previously cleared MiniMed™ 780G insulin pump as an alternate controller enabled (ACE) pump, completes the Medtronic FDA pre-market approval pathway for the Instinct sensor integration with our MiniMed™ 780G system for people living with type 1 diabetes. The Instinct sensor, designed exclusively by Abbott for MiniMed™ automated insulin delivery (AID) and Smart MDI systems, is the world's smallest[1,2], thinnest[1], most discreet[2] integrated CGM (iCGM) and offers a wear time of up to 15 days.

In the coming weeks, Medtronic and Abbott plan to complete their required compliance documentation enabling sensor integration and marketing. Completion of this step will promptly finalize the regulatory process, after which ordering for the Instinct sensor with the MiniMed™ 780G system will begin. Existing customers will have priority access through the Innovations Program. Pre-orders for Simplera Sync™ sensor will also begin later this month.

"We're working together to do what's best for people living with diabetes," said Chris Scoggins, Executive Vice President of Abbott's diabetes care business. "Abbott's biowearable technology has long set the standard for accurate, accessible, easy-to-use continuous glucose monitoring. Connecting it with the MiniMed™ 780G system aims to reduce the mental load of daily management, making it easier for people to live with diabetes."

Expanding Indications for Type 2 Diabetes
Separately, the FDA approved the MiniMed™ 780G system for people with insulin-requiring type 2 diabetes, making it the first and only automated insulin delivery (AID) system with Meal Detection™ technology* available to this population.

"This approval extends the benefits of automated insulin delivery to people with type 2 diabetes," said Natalie Bellini, DNP, FNP, BC-ADM, CDCES, Endocrine Nurse Practitioner and Program Director for Diabetes Technology at University Hospitals in Cleveland, Ohio. "It also aligns with the ADA Standards of Care, which now formally endorse AID systems for individuals with type 2 diabetes on intensive insulin therapy."

People living with type 2 diabetes who require insulin face daily challenges that affect both their physical health and emotional well-being, including frequent injections, meal planning, and glucose monitoring. Clinical evidence demonstrates that use of the MiniMed™ 780G system can improve glycemic outcomes and reduce treatment burden.

- In a recently published pivotal trial[3] (n=95) with the Guardian™ 4 sensor and Simplera Sync™ sensor, participants experienced a 0.7% reduction in HbA1c (from a baseline of 7.9%) and an increase in Time in Range to 81% (from a baseline of 72%), with minimal hypoglycemia.
- In a separate single-arm study[4] (n=236), A1C decreased from 7.7% to 6.9%, and Time in Range increased from 76.4% to 84.9% during 90 days of advanced hybrid closed-loop use with low time-below-range (70 mg/dL) of 0.3%. Participants also reported improvements in quality of life and reductions in diabetes distress.

The MiniMed™ 780G system is currently available for type 2 diabetes with the Guardian™ 4 sensor and will be available with Simplera Sync™ sensor when pre-orders begin later this month. Medtronic also plans to submit 510(k) applications seeking clearance for an interoperable pump indicated for type 2 diabetes, which would enable future integration with the Instinct sensor.

About the Diabetes Business at Medtronic
Medtronic Diabetes is on a mission to make diabetes more predictable, so everyone can embrace life to the fullest with the most advanced diabetes technology and always-on support when and how they need it. We've pioneered first-of-its-kind innovations for over 40 years and are committed to designing the future of diabetes management through next-generation sensors (CGM), intelligent dosing systems, and the power of data science and AI while always putting the customer experience at the forefront.

About Medtronic
Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow Medtronic on LinkedIn.

Cautions Regarding Forward Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which are subject to risks and uncertainties, including risks related to Medtronic's ability to satisfy the necessary conditions to consummate the separation of its Diabetes business on a timely basis or at all. Medtronic's ability to successfully separate its Diabetes business and realize the anticipated benefits from the separation (including consummating the transaction on a basis that is generally tax-free to shareholders), MiniMed's ability to succeed as a standalone publicly traded company, competitive factors, difficulties and delays inherent in the development, manufacturing, marketing and sale of medical products, government regulation, geopolitical conflicts, changing global trade policies, general economic conditions, and other risks and uncertainties described in the company's periodic reports on file with the U.S. Securities and Exchange Commission including the most recent Annual Report on Form 10-K of Medtronic. In some cases, you can identify these statements by forward-looking words or expressions, such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "looking ahead," "may," "plan," "possible," "potential," "project," "should," "going to," "will," and similar words or expressions, the negative or plural of such words or expressions and other comparable terminology. Actual results may differ materially from anticipated results. Medtronic does not undertake to update its forward-looking statements or any of the information contained in this press release, including to reflect future events or circumstances.

**Taking a bolus 15 – 20 min before a meal helps to keep blood sugar levels under control after eating.*

- Among applied sensors.
- Data on file. Abbott Diabetes Care, Inc.
- Bhargava A, Bergenstal RM, Warren ML, et al. Safety and Effectiveness of MiniMed™ 780G Advanced Hybrid Closed-Loop Insulin Intensification in Adults with Insulin-Requiring Type 2 Diabetes. *Diabetes Technol Ther.* 2025 May;27(5):366-375
- Carlson AL, Thrasher JR, Bhargava A, et al; IMPACT2D Study Group. Safety and Glycemic Outcomes During MiniMed 780G System use with the Disposable, All-in-one Simplera Sync Sensor in People with Type 2 Diabetes; Presented at: American Diabetes Association 85th Scientific Sessions; June 2025; Chicago, Illinois

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Additional assets available online: Photos

https://stage.mediaroom.com/minimed_mr/2025-09-02-FDA-Clears-MiniMed-TM-780G-System-to-Enable-Integration-with-the-Instinct-Sensor,-Made-by-Abbott,-and-Approves-Use-in-Type-2-Diabetes