

# 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<sup>1,2</sup>, thinnest<sup>1</sup>, most discreet<sup>2</sup> 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 Simpler 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<sup>3</sup> (n=95) with the Guardian™ 4 sensor and Simpler 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<sup>4</sup> (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.

