

Medtronic secures CE Mark for MiniMed™ 780G System for insulin-requiring people with diabetes including expanded indications in children as young as two, during pregnancy, and for type 2 diabetes

GALWAY, Ireland, July 21, 2025 [/PRNewswire/](#) -- Medtronic plc (NYSE: MDT), a global leader in medical technology, today announced CE (Conformité Européenne) Mark in Europe to expand indications of the MiniMed™ 780G system for use by individuals aged 2 years and older, during pregnancy, as well as type 2 insulin-requiring diabetes. To gain CE Mark for this expansion of indications, published clinical data in 2–6-year-olds, pregnant women, and people living with type 2 diabetes was reviewed. This expanded indication underscores the commitment Medtronic has to advancing access to automated insulin delivery (AID) technology for broader and more diverse populations, helping to improve outcomes and quality of life for people at every stage of life living with diabetes.

Expanded age indication extends benefits of AID systems for young children with type 1 diabetes

Data from the LENNY trial, recently published in [The Lancet Diabetes & Endocrinology](#), demonstrated the safety and efficacyⁱ of the MiniMed™ 780G system in children aged 2-6 years old with type 1 diabetes (T1D). Participants in the multi-center, randomized controlled, crossover trial achieved a 0.6% lower HbA1C and 9.9% higher time in range (TIR) when the system was used in auto mode, compared to those using it in manual mode. Parents and caregivers also reported improved sleep quality and lower fear of hypoglycemia when the system was used in auto mode.

"As a parent, nothing is more important than giving my child the freedom to just be a kid — but managing type 1 diabetes made that feel nearly impossible," said Paul Schulz, based in Barcelona, Spain, whose son Marc lives with type 1 diabetes. "Ever since Marc was diagnosed with diabetes at age 4, we have been lucky to count on support from Medtronic. This doesn't mean it has always been easy, but since starting the MiniMed™ 780G system, so much has changed. It's like we've gained a teammate — one that works around the clock to help manage his diabetes. It's very freeing."

Automated insulin delivery (AID) systems are rapidly becoming the standard of care for children with type 1 diabetes across Europe. In England and Wales, [NICE guidelines \(TA943\)](#) recommend hybrid closed-loop systems for all children and adolescents with T1D. Recognizing the importance of AID therapy, NHS England has a 5-year plan to roll out AID systems to most people with T1D, with children up to the age of 18 years old being prioritized because of their high need to optimize care. [2023 guidelines](#)ⁱⁱ from the German Diabetes Association advise offering AID to all pediatric patients, provided they or their caregivers can use the technology safely. In addition, the 2024 ISPAD guidelinesⁱⁱⁱ strongly recommend AID systems to improve time in range, reduce hypo- and hyperglycemia, enhance quality of life, and ease the burden of care — especially overnight.

"Advancements in Automated Insulin Delivery (AID) systems are revolutionizing how we care for children with type 1 diabetes," said Dr. Fiona Campbell, a leading pediatric endocrinologist in the UK. "For families, these systems lift the relentless burden of constant monitoring and insulin adjustments. Better glucose control in children can support healthier growth and brain development, better sleep, and the freedom to simply enjoy being a child. It's a transformative shift in both outcomes and quality of life."

Navigating pregnancy with type 1 diabetes: A smarter, safer path forward

Pregnancy presents unique challenges for women with type 1 diabetes. Hormonal shifts and physiological changes can make glucose management more complex, while the developing baby is especially vulnerable to both high and fluctuating blood sugar levels. To protect both mother and child, clinical guidelines recommend a much tighter glucose target during pregnancy—known as Pregnancy Time in Range (TIRp)—set between 63 and 140 mg/dL (3.5-7.8 mmol/L).

This is where advanced technology like the MiniMed™ 780G system can make a meaningful difference. The system's ability to target glucose levels as low as 100 mg/dL (5.5 mmol/L) offers a powerful tool for achieving tighter control. In a European study^{iv} evaluating its use during pregnancy, women using the MiniMed™ 780G system achieved an average TIRp of 66.5%—a significant improvement over traditional insulin therapy. The system also delivered better overnight glucose control, reduced overall and nighttime hypoglycemia, and higher treatment satisfaction among expectant mothers. These outcomes align with a growing body of evidence and a recent Clinical Practice Guideline jointly published by the European Society of Endocrinology and the U.S. Endocrine Society^v supporting the use of AID systems with the goal of improving maternal and fetal health outcomes during pregnancy.

MiniMed™ 780G system now indicated for type 2 diabetes

The MiniMed™ 780G system is now also approved for use in Europe for people with type 2 diabetes. In a recently published^{vi} multi-center, pivotal trial in 95 people with type 2 diabetes, the use of the MiniMed™ 780G system resulted in a 0.7% reduction in HbA1c (from a baseline of 7.9%) and an increase in TIR to 80% (from a baseline of 72%) with a time below range (70 mg/dL; 3.9 mmol/L) under 0.5%. Additionally, real-world data^{vii} of 26,427 MiniMed™ 780G system users who were identified as having type 2 diabetes (based on self-reported diagnosis and/or total daily insulin dose), demonstrated good glycemic control, on average exceeding the international consensus of 70% time in range (70-180 mg/dL) and maintaining time below range of less than 1%.

In the U.S., Medtronic is actively working with regulatory authorities to bring the benefits of advanced diabetes technology to a broader population. A submission to expand the use of the MiniMed™ 780G system for individuals with type 2 diabetes is currently under review by the U.S. Food and Drug Administration (FDA). Additionally, U.S. clinical trials are underway to examine the use of the MiniMed™ 780G system in 2–6-year-olds.

About the MiniMed™ 780G system

The MiniMed™ 780G system is the most advanced insulin pump system from Medtronic. The MiniMed™ 780G system's SmartGuard algorithm (also referred to as the advanced hybrid closed-loop algorithm) automates the delivery of insulin every five minutes — personalizing these doses to auto-correct[†] highs every five minutes based on CGM readings.[§] The system is designed to be used at a target glucose of 100 mg/dl (5.5 mmol/L) that can be adjusted and personalized on an individual basis.

† Refers to auto correct, which provides bolus assistance. Can deliver all auto correction doses automatically without user interaction, feature can be turned on and off.

§ Refers to SmartGuard™ feature. Individual results may vary.

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 (NYSE: MDT), visit www.Medtronic.com and follow on [LinkedIn](#).

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

Contacts:

Andrew Crawford
Global Communications
+41 79 378 1932

Ryan Weispfenning
Investor Relations
+1-763-505-4626

ⁱ Battelino et al. Efficacy and safety of automated insulin delivery in children aged 2–6 years (LENNY): an open-label, multicentre, randomised, crossover trial; Lancet Diabetes Endocrinol 2025

ⁱⁱ Deutsche Diabetes Gesellschaft Diagnostik, Therapie und Verlaufskontrolle des Diabetes mellitus im Kindes- und Jugendalter 2023, Version 4, AWMF-Registernummer: 057-016

ⁱⁱⁱ [ISPAD Clinical Practice Consensus Guidelines 2024: Diabetes technologies: Insulin delivery](#).

^{iv} Benhalima K, Beunen K, Van Wilder N, et al. Comparing advanced hybrid closed loop therapy and standard insulin therapy in pregnant women with type 1 diabetes (CRISTAL): a parallel-group, open-label, randomised controlled trial. Lancet Diabetes Endocrinol 2024

^v Wykoff JA et al. J Clin Endo Metab 2025; July 13:dgaf288.<https://doi.org/10.1210/clinem/dgaf288>.

^{vi} Bhargava A et al. Diab Tech Ther 2025; 27(5):366-375

^{vii} Thijs I, et al. J Diabetes Sci Technol. 2025 Mar 12:19322968251318373.

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<https://news.medtronic.com/2025-07-21-Medtronic-secures-CE-Mark-for-MiniMed-TM-780G-System-for-insulin-requiring-people-with-diabetes-including-expanded-indications-in-children-as-young-as-two-during-pregnancy.-and-for-type-2-diabetes>