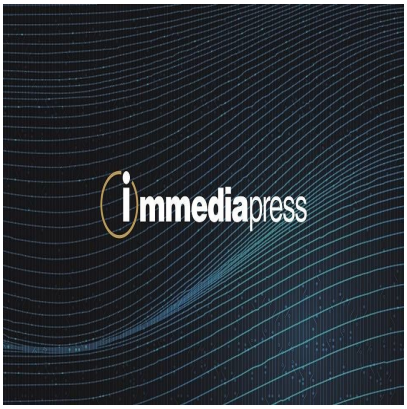

Hedia Secures Regulatory Approval to Expand Digital Diabetes Care to Pediatric Patients

Descrizione

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Updated MDR certification unlocks pediatric care, broader insulin regimen support, and expanded device connectivity across Hediaâ??s standalone app and partner platforms.

COPENHAGEN, Denmark, Sept. 22, 2026 /PRNewswire/ â?? Danish digital therapeutics company Hedia announced a major regulatory milestone, having secured official Medical Device Regulation (MDR) certification to expand its digital diabetes support to pediatric care. This clearance grants Hedia the right to remove its previous 18+ age restriction, paving the way for parents, guardians, and caregivers to use the Hedia Diabetes Assistant for children and teens under 18, alongside direct use by adults.

For families navigating type 1 diabetes in children, this approval enables simpler, collaborative care. The update will make pediatric support available both in the standalone Hedia app and integrated within partner digital health platforms, ensuring continuity in clinical workflows.

Furthermore, the certification enables flexible insulin regimens with broader treatment settings, which can be tailored to young patients. It also unlocks expanded data capabilities, offering seamless connectivity across continuous glucose monitors (CGMs), smart pens, smartwatches, and mobile health platforms.

Rasmus Kofoed, CEO of Hedia, commented:

â??Securing this regulatory milestone allows us to expand our focus to pediatric clinics and the dedicated teams caring for young patients. Managing diabetes in children requires precision, flexibility, and trust. By lifting the age restriction and gaining approval for broader regimen and device support, we are positioned to build the connections necessary to link clinics directly with families at home. Our goal is to streamline how healthcare professionals, caregivers, and patients access data, making daily

management simpler, safer, and more connected.â?•

By bridging the gap between home care, device data, and clinic oversight, Hedia is poised to streamline daily diabetes care for families while supporting better glycemic control. Development and rollout of these features will begin shortly.

About Hedia

Founded in 2016, Hedia develops digital therapeutics solutions that help adults, children, and families with insulin-dependent diabetes manage insulin therapy. The Hedia Diabetes Assistant supports insulin dose calculations using glucose data from connected continuous glucose monitors (CGMs), blood glucose monitors (BGMs), and smart pens, carbohydrate counting through an integrated food database, and physical activity support. Hedia works with healthcare providers, clinical teams, and digital health partners to improve diabetes management through connected, data-driven care.

Website: www.hedia.com

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