



## Insulet's Omnipod DASH™ System Now FDA Cleared as an Alternate Controller Enabled (ACE) Infusion Pump

September 23, 2019

ACTON, Mass.--(BUSINESS WIRE)--Sep. 23, 2019-- Insulet Corporation (NASDAQ: PODD) (Insulet), the global leader in [tubeless insulin pump](#) technology with its Omnipod® Insulin Management System, today announced it has received clearance from the U.S. Food and Drug Administration (FDA) for an Alternate Controller Enabled Infusion Pump (ACE Pump). This allows Insulet to market its Omnipod DASH™ Insulin Management System (Omnipod DASH System) as an integrated insulin pump (Omnipod DASH ACE Pump), allowing it to be a part of an interoperable automated insulin delivery (AID) system, such as the Company's Omnipod Horizon™ Automated Insulin Delivery System<sup>1</sup>.

The Omnipod DASH System has shown that it meets the FDA-established special controls that outline requirements for assuring the accuracy, reliability, cybersecurity and clinical relevance of ACE pumps. The cleared indication for the Omnipod DASH System states that the pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, and to receive, execute, and confirm commands from these devices.

"The diabetes industry is a dynamic and evolving landscape with technological and regulatory advancements enabling more interoperability and more patient choice in treatments and disease management," said Shacey Petrovic, President and Chief Executive Officer. "Omnipod DASH was designed with interoperability in mind, and we're thrilled to provide people with diabetes the choice and flexibility to manage their diabetes on their own terms. We commend the FDA's interoperability efforts and look forward to working with the Agency as we continue to deliver our robust innovation pipeline."

### **About the Omnipod DASH System:**

Insulet's Omnipod DASH System was designed to serve as the foundation for the Company's future innovation. Designed with user discretion and convenience in mind, the Omnipod DASH System is a continuous insulin delivery system consisting of two simple components: a tubeless, waterproof\*, Bluetooth® wireless technology Pod (pump) that holds up to 200 units of U-100 insulin and a modern, color touch-screen Personal Diabetes Manager (PDM) that controls the Pod. The Omnipod DASH System has a suite of optional mobile apps for users, caregivers and HCPs to help simplify diabetes management. The Omnipod DASH System, which received FDA clearance in June 2018, is the only [DTSec](#) and [ISO 27001](#) certified insulin pump for cyber and information security and safety.

### **About ACE Pumps:**

According to the FDA, ACE pumps are devices intended for the infusion of drugs into a patient. The ACE pump may include basal and bolus drug delivery at set or variable rates. ACE pumps are designed to reliably and securely communicate with compatible external devices, such as automated drug dosing systems, to allow drug delivery commands to be received, executed, and confirmed. ACE pumps are intended to be used both alone and in conjunction with digitally connected medical devices for the purpose of drug delivery.

### **About Insulet Corporation:**

Insulet Corporation (NASDAQ: PODD), headquartered in Massachusetts, is an innovative medical device company dedicated to making the lives of people with diabetes and other conditions easier through the use of its Omnipod product platform. The Omnipod Insulin Management System provides a unique alternative to traditional insulin delivery methods. With its simple, wearable design, the disposable Pod provides up to three days of non-stop insulin delivery, without the need to see or handle a needle. Insulet also leverages the unique design of its Pod, by tailoring its Omnipod technology platform for the delivery of non-insulin subcutaneous drugs across other therapeutic areas.

For more information, please visit: [www.insulet.com](http://www.insulet.com) and [www.myomnipod.com](http://www.myomnipod.com).

### **Forward-Looking Statement:**

This press release may contain forward-looking statements concerning Insulet's expectations, anticipations, intentions, beliefs or strategies regarding the future. These forward-looking statements are based on its current expectations and beliefs concerning future developments and their potential effects on Insulet. There can be no assurance that future developments affecting Insulet will be those that it has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond its control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements, and other risks and uncertainties described in its Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission in February 2019 in the section entitled "Risk Factors," and in its other filings from time to time with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of its assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Insulet undertakes no obligation to publicly update or revise any forward-looking statements.

*\*The Pod has a waterproof IP28 rating for up to 25 feet for 60 minutes. The PDM is not waterproof.*

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<sup>1</sup> CAUTION: Omnipod Horizon is an investigational device. Limited by United States Law to Investigational Use.

Source: Insulet Corporation

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