Declaration of Conformity

Manufacturer:

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Product:

Omnipod DASH Insulin Management System
(PDM and Pod – Package of 10, including fill syringe and fill needle)

Classification:

IIb, Rule 11, according to Annex IX of 93/42/EEC

Conformity Assessment Route:

Annex II of the MDD, excluding Section 4

Insulet declares under our sole responsibility that the mentioned products are in accordance with Annex II as confirmed by Notified Body BSI, and meet the provisions of the following:

Council Directive 93/42/EEC concerning Medical Devices (MDD)

Insulet declares that the radio transmitting equipment used in this System under the scope of the following Directive and was tested in accordance to Article 3, via internal production controls set out in Annex II, and that all essential radio test suites, as defined in the Essential Requirements, have been carried out:

Directive 2014/53/EU on Radio Equipment Direcitive (RED)

All supporting documentation is retained under the premises of the manufacturer.

The following product list identifies the products by part number, model number and description for Omnipod DASH Insulin Management System product line:

Part No.	Ref/Model No.	Description
18460	POD-BLE-I1-520	ASM, Pod Tray, Sealed, Dash FFS
PT-000086	POD-BLE-I1-520	ASM, Pod Tray, Sealed, SAW Dash FFS
18325	POD-BLE-I1-525	ASM, Pod, 5-Pack, Sterile, Dash
18320	POD-BLE-I1-529	ASM, Pod, 10-Pack, Sterile, Dash
PT-000010	INT1-D001-MG	ASM, Omnipod, INTL Dash, PDM, (mg/dL)
PT-000011	INT2-D001-MM	ASM, Omnipod, INTL Dash, PDM, (mmol/l)
PT-000019-<CCC>-<LLL>-MG*	SKT-<CCC>-D001-MG-<LLL>	ASM, Final DASH PDM kit, <Country>-<Language>, (mg/dL)
PT-000019-<CCC>-<LLL>-MM*	SKT-<CCC>-D001-MM-<LLL>	ASM, Final DASH PDM kit, <Country>-<Language>, (mmol/l)
PT-000115	<LLL>-SKS-10-MM	ASM, Starter Set, <Language>, Dash International, mmol
PT-000114	<LLL>-SKS-10-MG	ASM, Starter Set, <Language>, Dash International, mgdl

<CCC> = 3-letter country code
<LLL> = 3-letter language code
*The addition of MG or MM to part numbers is used as applicable and does not apply to all part numbers.

The Omnipod DASH Insulin Management System complies with the following standards as applicable:

Standard	Title
EN 301 489-1	Electromagnetic compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 301-489-3	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz
EN 300-328	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 556-1	Sterilization of medical devices; Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices
EN 1041	Information supplied by the manufacturer of medical devices
EN 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 60601-1-8	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 60601-1-11	Medical Electrical Equpiment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard – Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
EN 60601-2-24	Medical electrical equipment – Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers
EN 62304	Medical device software – Software lifecycle processes
BS EN 62366	Medical devices – Part 1: Application of usability engineering to medical devices
BS EN ISO 13485	Medical Devices. Quality Management Systems. Requirements for regulatory purposes.
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4	Biological Evaluation of Medical Devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity
EN ISO 10993-6	Biological evaluation of medical devices – Part 6: Test for local effects after implantation
EN ISO 10993-7	Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals
EN ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-17	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18	Biological evaluation of medical devices – Part 18: Chemical characterization of materials
EN ISO 11135-1	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

Standard	Title
EN ISO 14971	Medical Devices – Application of risk management to medical devices
EN ISO 15223-1	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

Notified Body: BSI
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Identification Number: 2797

EC Certificate: CE 612985

Julie Perkins
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Insulet Corporation

10 March 2021
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Revision History			
Rev	Change Order #	Description	Effectivity Date
005	DCO-003215	Updated Authorized Representative.	09MAR2021