

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 612985  
**Issued To:** Insulet Corporation  
100 Nagog Park  
Acton  
Massachusetts  
01720  
USA

In respect of:

**Design and manufacture of infusion pump systems for the delivery of:**  
**-insulin, with and without automated insulin delivery software, and the measurement of blood glucose in the treatment of diabetes mellitus, and**  
**-a female fertility drug in the treatment of female infertility, and**  
**-a dopamine agonist drug for the treatment of Parkinson's disease.**  
**Those aspects of Annex II concerned with securing and maintaining sterile conditions of an adhesive overlay accessory.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-04-10**

Date: **2021-04-07**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 612985

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NBOG code(s)	Device description	Intended purpose
<b>Class IIb</b>		
MD 1101, MD 1302, MDS 7010	Infusion pump systems for the delivery of insulin and the measurement of blood glucose	Treatment of diabetes mellitus
MD 1101, MDS 7010	Infusion pump system for the delivery of a female fertility drug	Treatment of female infertility
MD 1101, MDS 7010	Infusion pump system for the delivery of a dopamine agonist drug	Treatment of Parkinson's disease
<b>Class Is</b>		
MDS 7006	Adhesive overlay accessory	N/A

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Abbott Diabetes Care Inc. 1360 South Loop Road Alameda California 94502 USA	<b>Manufacture</b>
B. Braun Medical Inc. 824 Twelfth Avenue Bethlehem Pennsylvania 18018 USA	<b>Manufacture</b>
Flextronics Industrial (Shenzhen) Co., Ltd. 7/F, Building 1, 1/F, 3A/F, 5-7/F, Building 2 and 1-4/F, Building 3, Rundongsheng Industrial Park Longzhu Xixiang, Baoan District 518126 Shenzhen Guangdong China	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Insulet Corporation 600 Technology Park Drive Suite 200 Billerica Massachusetts 01821 USA	<b>Design</b>
Insulet Corporation 9276 Scranton Rd 4th Floor San Diego California 92121 USA	<b>Software</b>
Insulet Corporation 14 Progress Road Billerica Massachusetts 01820 USA	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Insulet Netherlands B.V. WTC Utrecht Stadsplateau 7 Suite 7.06 3521 AZ Utrecht The Netherlands	<b>EU Representative</b>
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	<b>ETO Sterilization</b>
Sanmina- SCI Systems (Kunshan) Co., Ltd 312, Qing Yang South Road Economic & Technical Development Zone Kunshan, Jiangsu Province 215300 China	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterigenics Belgium (Petit- Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 B-4800 Verviers Belgium	<b>ETO Sterilization</b>
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	<b>ETO Sterilization</b>
Synergy Health Ede BV (Location AST Venlo) Faunalaan 38 Venlo 5928 RZ The Netherlands	<b>ETO Sterilization</b>

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Date	Reference Number	Action
10 April 2014	8137171	First issue, transfer from another Notified Body
03 July 2014	8181215	Addition of Abbott Diabetes Care Inc. and B.Braun Medical Inc. as significant subcontractors for manufacture
04 December 2014	8239659	Change of address from 9 Oak Park Drive, Bedford, Massachusetts, 01730, USA to 600 Technology Park Drive, Suite 200, Billerica, Massachusetts 01821, USA Addition of LifeScan Europe, a division of Cilag GmbH International to the List of Significant Subcontractors
27 May 2015	8297597	Certificate renewal. Addition of STERIS Isomedix as a significant subcontractor for ETO sterilization. Removal of LifeScan Europe and MedPlast Tempe as significant subcontractors.
07 April 2017	8604542	Extension to scope to include delivery of a dopamine agonist for the treatment of Parkinson's disease. Addition of Insulet Corporation location in San Diego as a significant subcontractor for software development.
06 December 2017	8859521	Relocation of Insulet Corporation in San Diego, California, to a different suite at the same address. Addition of Sterigenics US, LLC as a significant subcontractor for ETO sterilization. Removal of professional contract sterilization, Inc.
25 February 2019	9737477	Traceable to NB 0086.

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Date	Reference Number	Action
30 September 2019	9715182	Certificate Renewal. Change of legal manufacturer address from 600 Technology Park Drive, Billerica to 100 Nagog Park, Acton, Massachusetts. Addition of Insulet site at 600 Technology Park Drive, Billerica, Massachusetts as a significant subcontractor for design and Insulet site at 14 Progress Road, Billerica, Massachusetts as a significant subcontractor for manufacture. Addition of Sterigenics Belgium (Petit- Rechain) SA as a significant subcontractor for ETO sterilization. Change of address of significant subcontractor Flextronics Industrial (Shenzhen) Co., Ltd. Extension to scope to include sterile adhesive overlay accessory. Addition of device table.
07 April 2020	9750334	Extension to the previous certificate scope to add automated insulin delivery software. Addition of Synergy Health Ede BV, The Netherlands (Venlo) as a significant subcontractor for ETO sterilization. Change of address of significant subcontractor Insulet Corporation in San Diego from 4370 La Jolla Village Drive Northern Trust Building to 9276 Scranton Rd 4th Floor.



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Date	Reference Number	Action
17 September 2020	3271525	Re-issue for addition of Sanmina- SCI Systems (Kunshan), 312, Qing Yang South Road, Economic & Technical Development Zone, Kunshan, Jiangsu Province, 215300, China as significant subcontractor for manufacture. Correction of the zip code for Insulet Corporation, 14 Progress Road, Billerica Massachusetts: updated from 01820 to 01821.
Current	3411851	Change of EU representative (Healthlink Europe B.V. changed to Insulet Netherlands B.V.)