

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. CE 603082
Issued To: **Abbott Diabetes Care Limited**
Range Road
Witney
Oxon
OX29 0YL
United Kingdom

In respect of:

The design, development and manufacture of blood glucose and blood ketone measuring systems for self-testing, including meters, test strips and control solutions.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

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: **2013-09-17**

Date: **2020-12-24**

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. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.

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

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Supplementary Information to CE 603082

Issued To:

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NBOG Code	Device Name	Intended Purpose
Annex II List B		
IVD 0309	<ol style="list-style-type: none"> 1. Optium Xido Neo Blood Glucose and Ketone Monitoring System 2. FreeStyle Precision Neo Blood Glucose and Ketone Monitoring System 3. FreeStyle Optium Neo Blood Glucose and Ketone Monitoring System 	Devices for measuring glucose and ketone (β -hydroxybutyrate) in blood samples. For self testing or professional use.
IVD 0309	<ol style="list-style-type: none"> 1. FreeStyle Lite Blood Glucose Monitoring System 2. FreeStyle Freedom Lite Blood Glucose Monitoring System 3. FreeStyle Papillon Vision Blood Glucose Monitoring System 	Devices for measuring glucose in blood samples. For self testing or professional use.
IVD 0309	<ol style="list-style-type: none"> 1. Optium Xido Blood Glucose Test Strips 2. FreeStyle Precision Blood Glucose Test Strip 3. FreeStyle Optium Blood Glucose Test Strips 	Devices for measuring glucose in blood samples. For self testing or professional use.
IVD 0309	<ol style="list-style-type: none"> 1. FreeStyle Lite Blood Glucose Test Strips 2. FreeStyle Blood Glucose Test Strips 3. FreeStyle Papillon Easy Blood Glucose Test Strips 4. FreeStyle Lite Blood Glucose Monitoring System Maintenance Kit 	Devices for measuring glucose in blood samples. For self testing or professional use.
IVD 0309	<ol style="list-style-type: none"> 1. MediSense Glucose & Ketone Control Solution 2. Freestyle Control Solution 	Devices for use in verifying meter and test strip function. For self testing or professional use.

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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.

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NBOG Code	Device Name	Intended Purpose
Non-Annex II Self Test		
IVD 0401	1. FreeStyle Precision Blood β -Ketone Test Strips 2. FreeStyle Optium Blood β -Ketone Test Strips 3. Optium Xido β -Ketone Test Strips	Devices for measuring ketone (β -hydroxybutyrate) in blood samples. For self-testing or professional use.

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List of Significant Subcontractors

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

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Issued To: **Abbott Diabetes Care Limited**
Range Road
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Oxon
OX29 0YL
United Kingdom

Subcontractor:	Service(s) supplied
Abbott B.V. Wegalaan 9 2132 JD Hoofddorp The Netherlands	EU Representative
Abbott Diabetes Care Inc. 1360 South Loop Road Alameda California 94502 USA	Design
Abbott Ireland, Diabetes Care Division Donegal Town Co. Donegal F94 FX36 Ireland	Manufacture
Banta Global Turnkey (Singapore) Pte Ltd 30 Toh Guan Road #05-01, 608840 Singapore	Packaging

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Subcontractor:	Service(s) supplied
Bionostics, Inc. 7 Jackson Road Devens, MA 01434 USA	Manufacture
Flextronics Manufacturing Aguascalientes SA de CV Boulevard a Zacatecas Km. 9.5 Jesus Maria Aguascalientes 20900 Mexico	Manufacture
Flextronics Technology (Shenzhen) Co., Ltd. 3-6/F, Building 1, 3B/F, 4/F, Building 2, and 5-7/F, Building 3, Rundongsheng Industrial Park, Longzhu, Xixiang, Baoan District, 518126, Shenzhen, Guangdong People's Republic of China	Manufacture

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Subcontractor:

Service(s) supplied

RR Donnelley GTS Poland Sp. z o.o.
ul. Zakladowa 90 lok. 92
92-402 Lodz
Poland

**Packaging
Testing**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 603082**
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Date	Reference Number	Action
17 September 2013	8032251	First issue. Transfer from another Notified Body.
06 August 2014	8094206	Changed "Ltd." to "Limited" on certificate holder's name. Addition of Flextronics Manufacturing (Singapore) Pte Ltd as a significant subcontractor for manufacture and RR Donnelley Global Turnkey Solutions Poland Sp. z o.o. as a significant subcontractor for testing and packaging.
02 October 2015	8417219	Addition of Flextronics Manufacturing Aguascalientes SA de CV as a significant subcontractor for manufacture.
25 February 2016	8466119	Certificate renewal. Change in Scope.
12 February 2019	8075606	Traceable to NB 0086.
Current	9786610	Certificate renewal. Change of subcontractor address for Flextronics Technology (Shenzen) Co Ltd, Abbott Ireland, Diabetes Care, RR Donnelley Global Solutions. Removal of subcontractor Sanmina Ireland UC and Flextronic Singapore. Addition of subcontractors Abbott BV in The Netherlands, Abbott Diabetes Care Inc, Banta Singapore