

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **17 September 2013**

Date: **25 February 2016**

Expiry Date: **05 March 2021**

...making excellence a habit.™

Page 1 of 1

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.

EC Certificate - Full Quality Assurance

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

List of Significant Subcontractors

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

Certificate No: **CE 603082**
 Date: **25 February 2016**
 Issued To: **Abbott Diabetes Care Limited**
Range Road
Witney
Oxon
OX29 0YL
United Kingdom

Subcontractor:	Service(s) supplied
Abbott Ireland Diabetes Care Donegal Town Donegal Ireland	Manufacture
Bionostics, Inc. 7 Jackson Road Devens, MA 01434 USA	Manufacture
Flextronics Manufacturing (Singapore) Pte Ltd 1 Kallang Place 339211 Singapore	Manufacture
Flextronics Manufacturing Aguascalientes SA de CV Blvd. a Zacatecas Km. 9.5 Jesus Maria Aguascalientes 20900 Mexico	Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance

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

List of Significant Subcontractors

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

Certificate No: **CE 603082**
 Date: **25 February 2016**
 Issued To: **Abbott Diabetes Care Limited**
Range Road
Witney
Oxon
OX29 0YL
United Kingdom

Subcontractor:	Service(s) supplied
Flextronics Technology (Shenzhen) Co Ltd Building 1, Yusheng Industrial Park 467 Xixiang Section National Highway 107 Xixiang, Baoan District, 518126 Shenzhen, Guangdong China	Manufacture
RR Donnelley Global Turnkey Solutions Poland Sp. z o.o. ul. Zakladowa 90/92 Lodz 92-402 Poland	Packaging Testing
Sanmina Rathealy Road Fermoy, County Cork Ireland	Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 603082**
 Date: **25 February 2016**
 Issued To: **Abbott Diabetes Care Limited**
Range Road
Witney
Oxon
OX29 0YL
United Kingdom

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.

...making excellence a habit.™

Page 1 of 1

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.