

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 773378 R000

Manufacturer: Abbott Diabetes Care Limited

Address:

Range Road
Witney
Oxon
OX29 0YL
United Kingdom

Single Registration Number: GB-MF-000029309

EU Authorised Representative: Abbott B.V.

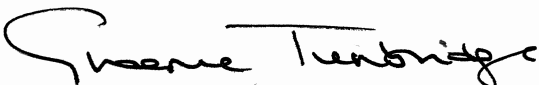
Address:

Wegalaan 9
2132 JD Hoofddorp
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

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



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-07-05**

Current Issue Date: **2023-12-19**

Starting Validity Date: **2023-12-19**

Expiry Date: **2028-07-04**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 773378 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The FreeStyle Optium, FreeStyle Precision and Optium Xido Blood Glucose Test Strips are in vitro medical devices intended for the automated quantitative measurement of glucose in fresh whole capillary blood samples from the fingertip for the monitoring of glucose levels in individuals with diabetes mellitus.

Risk Classification: Class C self-test and Near patient test

Basic UDI-DI: 5021791PGT0001HK

Type (Codes as per (EU) 2017/2185): IVR 0602

Device Name	Model
FreeStyle Optium Blood Glucose Test Strips	78614-01, 78624-01, 78625-01, 78648-01, 78649-01, 78650-01, 78651-01, 78693-01, 78694-01, 78695-01, 78697-01, 78701-01

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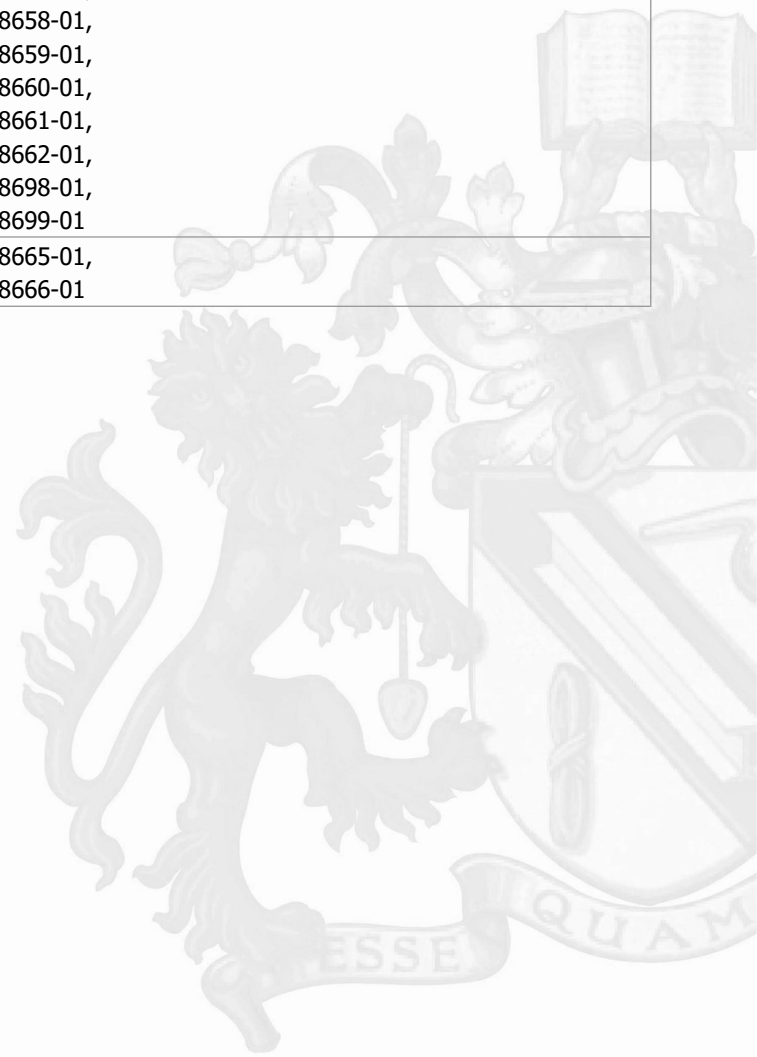
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Device Name	Model
FreeStyle Precision Blood Glucose Test Strips	78656-01, 78657-01, 78658-01, 78659-01, 78660-01, 78661-01, 78662-01, 78698-01, 78699-01
Optium Xido Blood Glucose Test Strips	78665-01, 78666-01



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IVDR 773378 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-07-05	3702136	Issued
Current	30061146	Amended – Classification corrected to also include Near patient test.



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

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

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 745236 R000

Manufacturer: Abbott Diabetes Care Ltd.

Address:

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Witney
Oxon
OX29 0YL
United Kingdom

Single Registration Number: GB-MF-000029309

EU Authorised Representative: Abbott B.V.

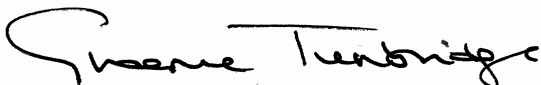
Address:

Wegalaan 9
2132 JD Hoofddorp
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

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



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-08-04**

Current Issue Date: **2023-12-18**

Starting Validity Date: **2023-12-18**

Expiry Date: **2027-08-03**

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EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 745236 R000

Device Schedule:

Class C near-patient test devices	Intended purpose
FreeStyle Precision Pro Blood β -Ketone Test Strips	See EU Technical Documentation Assessment Certificate – IVDR 746047
FreeStyle Precision H Blood β -Ketone Test Strips	
FreeStyle Optium H Blood β -Ketone Test Strips (FreeStyle Optium H β -Ketone Blood β -Ketone Test Strips)	
FreeStyle Precision Pro Blood Glucose Test Strips	See EU Technical Documentation Assessment Certificate – IVDR 746053
FreeStyle Precision Neo H Blood Glucose Test Strips	
FreeStyle Optium Neo H Blood Glucose Test Strips	
Class C Self-test and near-patient test devices	Intended purpose
FreeStyle Precision Blood β -Ketone Test Strips	See EU Technical Documentation Assessment Certificate – IVDR 773376
FreeStyle Optium Blood β -Ketone Test Strips (FreeStyle Optium β -Ketone Blood β -Ketone Test Strips)	
Optium Xido Blood β -Ketone Test Strips	See EU Technical Documentation Assessment Certificate – IVDR 773377
FreeStyle Lite Blood Glucose Test Strip	
FreeStyle Papillon Easy Blood Glucose Test Strip	
FreeStyle Lite Blood Glucose Monitoring System Maintenance Kit	See EU Technical Documentation Assessment Certificate – IVDR 773378
FreeStyle Optium Blood Glucose Test Strips	
FreeStyle Precision Blood Glucose Test Strips	
Optium Xido Blood Glucose Test Strips	See EU Technical Documentation Assessment Certificate – IVDR 773379
FreeStyle Precision Neo meter	
FreeStyle Optium Neo meter	
Optium Xido Neo meter	See EU Technical Documentation Assessment Certificate – IVDR 773379
FreeStyle Precision Neo Blood Glucose and Ketone Meter (FreeStyle Precision Neo Blood Glucose and Ketone Monitoring System)	
FreeStyle Optium Neo Blood Glucose and Ketone Meter (FreeStyle Optium Neo Blood Glucose and Ketone Monitoring System)	
Optium Xido Neo Blood Glucose and Ketone Meter (Optium Xido Neo Blood Glucose and Ketone Monitoring System)	

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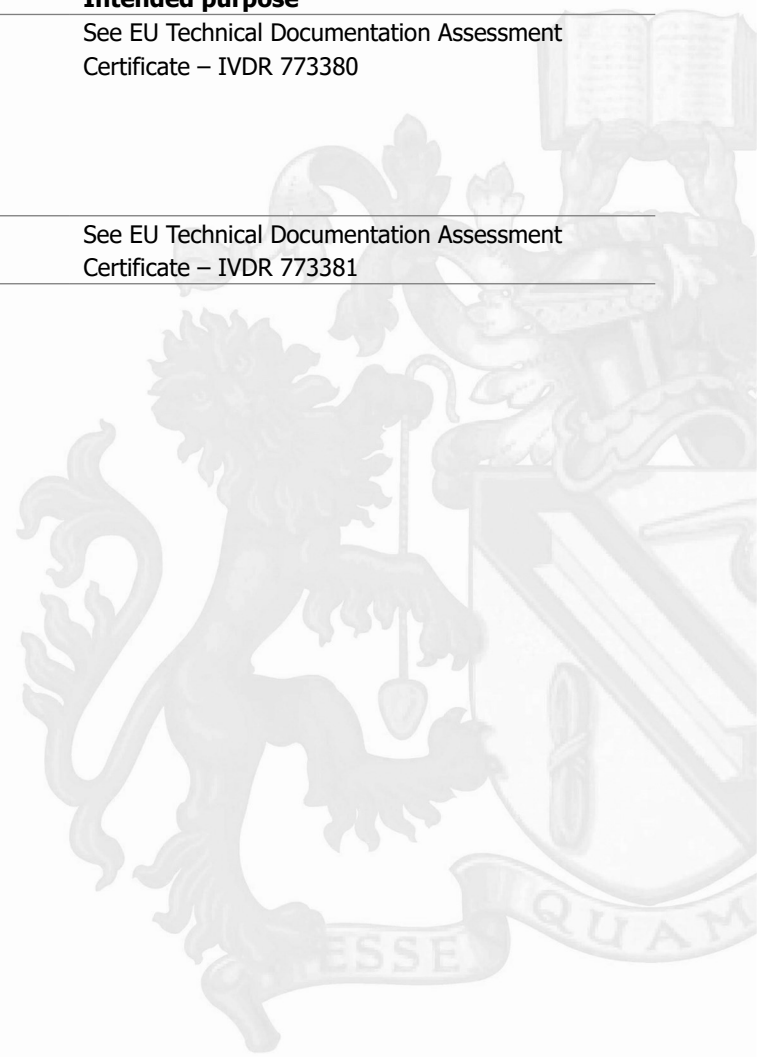
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Class C Self-test and near-patient test devices	Intended purpose
FreeStyle Freedom Lite Meter FreeStyle Freedom Lite Blood Glucose Monitoring System FreeStyle Freedom Lite Blood Glucose Start Kit. Variant of "Freestyle Freedom Lite Blood Glucose Monitoring System" FreeStyle Papillon Vision Blood Glucose Meter FreeStyle Papillon Vision Blood Glucose Monitoring System	See EU Technical Documentation Assessment Certificate – IVDR 773380
FreeStyle Lite Blood Glucose Meter FreeStyle Lite Blood Glucose Monitoring System	See EU Technical Documentation Assessment Certificate – IVDR 773381



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EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 745236 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-08-04	3392576	Issued
2023-07-05	3702142	Supplemented-Addition of the following devices: FreeStyle Precision Blood β -Ketone Test Strips. FreeStyle Optium Blood β -Ketone Test Strips. (FreeStyle Optium β -Ketone Blood β -Ketone Test Strips). Optium Xido Blood β -Ketone Test Strips. FreeStyle Lite Blood Glucose Test Strip. FreeStyle Papillon Easy Blood Glucose Test Strip. FreeStyle Lite Blood Glucose Monitoring System Maintenance Kit. FreeStyle Optium Blood Glucose Test Strips. FreeStyle Precision Blood Glucose Test Strips. Optium Xido Blood Glucose Test Strips.

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Date	Reference Number	Action
Current	30048406	<p>Supplemented - Addition of the following devices to new device group; "Class C self-test and near patient test devices":</p> <ul style="list-style-type: none"> FreeStyle Precision Neo meter FreeStyle Optium Neo meter Optium Xido Neo meter FreeStyle Precision Neo Blood Glucose and Ketone Meter (FreeStyle Precision Neo Blood Glucose and Ketone Monitoring System) FreeStyle Optium Neo Blood Glucose and Ketone Meter (FreeStyle Optium Neo Blood Glucose and Ketone Monitoring System) Optium Xido Neo Blood Glucose and Ketone Meter (Optium Xido Neo Blood Glucose and Ketone Monitoring System) FreeStyle Freedom Lite Meter FreeStyle Freedom Lite Blood Glucose Monitoring System FreeStyle Freedom Lite Blood Glucose Start Kit. Variant of "Freestyle Freedom Lite Blood Glucose Monitoring System" FreeStyle Papillon Vision Blood Glucose Meter FreeStyle Papillon Vision Blood Glucose Monitoring System FreeStyle Lite Blood Glucose Meter FreeStyle Lite Blood Glucose Monitoring System <p>Amended: Moved the following certified devices from "Class C near-patient test devices" group to "Class C Self-test and near-patient test devices":</p> <ul style="list-style-type: none"> FreeStyle Precision Blood β-Ketone Test Strips FreeStyle Optium Blood β-Ketone Test Strips (FreeStyle Optium β-Ketone Blood β-Ketone Test Strips) Optium Xido Blood β-Ketone Test Strips. FreeStyle Lite Blood Glucose Test Strip FreeStyle Papillon Easy Blood Glucose Test Strip

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Regulation (EU) 2017/746, Annex IX Chapter I and III

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Date	Reference Number	Action
		FreeStyle Lite Blood Glucose Monitoring System Maintenance Kit FreeStyle Optium Blood Glucose Test Strips FreeStyle Precision Blood Glucose Test Strips Optium Xido Blood Glucose Test Strips



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