

EU Technical Documentation Assessment Certificate

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

IVDR 773376 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.

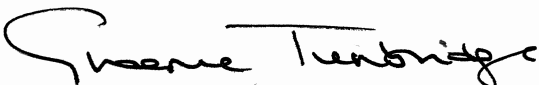
Address:

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 Global Regulatory & Quality

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

Current Issue Date: **2024-06-04**

Starting Validity Date: **2024-06-04**

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

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Device Schedule:

Intended Purpose as per the Instructions for Use:

The FreeStyle Precision Blood β -Ketone Test Strips, FreeStyle Optium Blood β -Ketone Test Strips and Optium Xido β -Ketone Test Strips are in vitro medical devices intended for the automated quantitative measurement of β hydroxybutyrate in fresh whole capillary blood from the fingertip or venous blood for the monitoring of ketone in individuals with diabetes mellitus and ketosis including diabetic ketoacidosis (DKA).

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

Basic UDI-DI: 5021791PKT0001K7

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

| Device Name | Model |
|---|--|
| FreeStyle Precision Blood β -Ketone Test Strips | 78663-01, 78664-01 78843-01 78844-01 |
| FreeStyle Optium Blood β -Ketone Test Strips (FreeStyle Optium β -Ketone Blood β -Ketone Test Strips) | 78617-01, 78653-01, 78690-01 78798-01 78804-01 78841-01 78842-01 |
| Optium Xido Blood β -Ketone Test Strips | 78667-01 |

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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 | 3702134 | Issued |
| 2023-12-19 | 30060756 | Amended – Classification corrected to also include Near patient test. Addition of model number 78798-01 for device FreeStyle Optium Blood β-Ketone Test Strips (FreeStyle Optium β-Ketone Blood β-Ketone Test Strips). |
| Current | 30129554 | Amended – Addition of model numbers 78804-01; 78841-01; 78842-01 for the FreeStyle Optium Blood β-Ketone Test Strips (FreeStyle Optium β-Ketone Blood β-Ketone Test Strips) and model numbers 78843-01; 78844-01 for FreeStyle Precision Blood β-Ketone Test Strips. |

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