EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 716262 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 examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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: **2020-02-13**

Current Issue Date: **2023-12-20**

Starting Validity Date: **2023-12-20**

Expiry Date: **2025-02-12**

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Device Schedule: Class III and Class IIb Devices

Class IIb	Intended Purpose
Continuous glucose monitoring systems, including sterile sensors, readers and mobile application software	Indicated for measuring interstitial fluid glucose levels in people (age 2 or older) with diabetes melitus

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Glucose Data Management Software	Class IIa
Continuous glucose monitoring sterile sensors and readers	Class IIa

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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
13 February 2020	3060275	Issued.
21 May 2020	3168806	Supplemented – Addition of Class IIa Glucose Data Management Software to certificate scope.
22 February 2021	3375532	Supplemented – Addition of Class IIa Continuous glucose monitoring sterile sensors and readers. Amended - Addition of critical subcontractor Newyu, Inc. Amended – Change of address to Flextronics Technology (Shenzhen) Co., Ltd. Amended – Change of subcontractor name Flextronics International USA from "Flextronics International USA, Inc. - HQ" to "Flextronics International USA, Inc." Amended – Change of the address for the Legal Manufacturer to add "Witney".
13 July 2021	3478784	Amended - Addition of subcontractor Flextronics America LLC Amended - Administrative update to prior history entries

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Date	Reference number	Action
Current	3917163	Supplemented - Addition of Class IIb continuous glucose monitoring systems with intended purpose age 2 or older. Amended - Change of subcontractor name. Amended - Addition of Single Registration Number. Restricted - Removal of FreeStyle Libre EX Flash Glucose Monitoring System (Reader Kit + Sensor Kit), from Class IIb continuous glucose monitoring systems device group, no longer placed on the market.

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