

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: Not Available

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 and Class IIb implantable 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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-02-13**

Date: **2021-07-13**

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

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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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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 4 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".
Current	3478784	Amended - Addition of subcontractor Flextronics America LLC Amended - Administrative update to prior history entries

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