EU Quality Management System Certificate

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

MDR 727974

Manufacturer: Dexcom, Inc.

Address:
6340 Sequence Drive
San Diego
California
92121
USA

Single Registration Number: US-MF-000010694

EU Authorised Representative: MDSS GmbH

Address:
Schiffgraben 41
30175 Hannover
Germany

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: **2022-03-08**

Current Issue Date: **2023-11-13**

Starting Validity Date: **2023-11-13**

Expiry Date: **2027-03-07**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Continuous Glucose Monitoring System including Sterile Sensors	Dexcom's Continuous Glucose Monitoring System is intended to continuously measure the glucose in the interstitial fluid and is designed to replace fingerstick blood glucose (BG) testing for treatment decisions.

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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
2022-03-08	3175473	First Issue; Traceable to CE 591560
Current	30003405	Amended – Clarification of Device Schedule from 'Dexcom G7 Continuous Glucose Monitoring System' to 'Continuous Glucose Monitoring System, including sterile sensors' Amended – Clarification of Intended Purpose Amended – Removal of subcontractor information Amended – Addition of subcontractors for aseptic processing and ETO sterilisation

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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.

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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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