By Royal Charter

EU Quality Management System Certificate

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

MDR 727974 R000

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 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):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-03-08** Date: **2022-03-08** Expiry Date: **2027-03-07**

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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
Dexcom G7 Continuous Glucose Monitoring System	The Dexcom G7 Continuous Glucose Monitoring System is a continuous glucose monitoring system 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
Current	3175473	First Issue; Traceable to CE 591560

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 727974 R000

Date: **2022-03-08**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
BBI Solutions (Formerly Maine Biotechnology Services) 1037R Forest Avenue Portland Maine 04103 USA	**Crucial Supplier**
DexCom, Inc. 232 South Dobson Road Mesa Arizona 85202 USA	**Manufacture**
Isomedix Operations, Inc. 1441 Don Haskins Drive El Paso Texas 79936 USA	**ETO Sterilization**
Sterigenics US, LLC 687 S. Wanamaker Avenue Ontario California 91761 USA	**ETO Sterilization**

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