dexcom
CONTINUOUS GLUCOSE MONITORING

Dexcom product Declarations of Conformity

dexcom
One Step Ahead

6340 Sequence Drive
San Diego, CA 92121
1-858-200-0203
Fax 1-858-332-0204
www.dexcom.com

EU DECLARATION OF CONFORMITY
RoHS Directive

Manufacturer's Name: DexCom, Inc.

Manufacturer's Address: 6340 Sequence Drive
San Diego, CA 92121
United States of America

Product Model/Name(s):

- STP- GS -(001 to 007)/ mg/dL, Dexcom G6 CGM System
- STP- GS -(100 to 112)/ mmol/L, Dexcom G6 CGM System
- STK- GS -(001 to 099)/ mg/dL, Dexcom G6 Receiver Kit
- STK- GS -(101 to 199)/ mmol/L, Dexcom G6 Receiver Kit
- STR- GS -(002 to 099)/ mg/dL, Dexcom G6 Replacement Receiver Kit
- STR- GS -(101 to 199)/ mmol/L, Dexcom G6 Replacement Receiver Kit
- STT- GS -(001 to 010)/ Dexcom G6 Transmitter Kit
- STS- GS -(002 to 144)/ Dexcom G6 Sensor
- STSGS002 and STSGS003/ Dexcom G6 Sensor

Directive: Restriction on the use of certain Hazardous Substances (RoHS)

Devices Comply with:

EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

This document is valid until the date of the certificate expiration of May 26th, 2024 unless superseded by a more recent revision.

We, the undersigned, hereby declare that the equipment specified above conforms to the above Standards.

Signature: _____ Date: 09 DEC 2021

Full Name: Chris Cuddy Position: Director Quality Assurance, Dexcom Inc.

dexcom
One Step Ahead

6340 Sequence Drive
San Diego, CA 92121
1-858-200-0203
Fax 1-858-332-0204
www.dexcom.com

EU DECLARATION OF CONFORMITY
Radio Equipment Directive

Manufacturer's Name: DexCom, Inc.

Manufacturer's Address: 6340 Sequence Drive
San Diego, CA 92121
United States of America

Product Model/Name(s):

- STP- GS -(001 to 007)/ mg/dL, Dexcom G6 CGM System
- STP- GS -(100 to 112)/ mmol/L, Dexcom G6 CGM System
- STK- GS -(001 to 099)/ mg/dL, Dexcom G6 Receiver Kit
- STK- GS -(101 to 199)/ mmol/L, Dexcom G6 Receiver Kit
- STR- GS -(002 to 099)/ mg/dL, Dexcom G6 Replacement Receiver Kit
- STR- GS -(101 to 199)/ mmol/L, Dexcom G6 Replacement Receiver Kit
- STT- GS -(001 to 010)/ Dexcom G6 Transmitter Kit
- STS- GS -(002 to 144)/ Dexcom G6 Sensor
- STSGS002 and STSGS003/ Dexcom G6 Sensor

Devices Comply with:

Frequency Band: 2402 – 2480 MHz
Output Power: -1.7dBm

The equipment described above is in conformity with the Directive 2014/53/EU, in accordance with the following harmonized standards:

Essential Requirements	Compliance Standard
Article 3(1)(a) Safety	EN 60601-1:2006/AMD1:2013
Article 3(1)(b) EMC	ETSI EN 301 489-1 V2.2.3 (2019-11), ETSI EN 301 489-17 (2017-03), EN 60601-1-2:2015
Article 3(2) Radio Spectrum Usage	ETSI EN 300 328 V2.2.2 (2019-07)
Article 3(3)	N/A, No delegated acts currently in force for radio equipment listed in this Declaration.

This document is valid until the date of the certificate expiration of May 26th, 2024 unless superseded by a more recent revision.

We, the undersigned, hereby declare that the equipment specified above conforms to the above Standards.

Signature: _____ Date: 09DEC2021

Full Name: Chris Cuddy Position: Director Quality Assurance, Dexcom Inc.

6340 Sequence Drive
San Diego, CA 92121
www.dexcom.com

EC DECLARATION OF CONFORMITY

Manufacturer Name:	Dexcom, Inc.
Manufacturer Address:	6340 Sequence Drive San Diego, CA 92121 United States of America
Manufacturer SRN:	US-MF-000010694

Authorised Representative Name:	MDSS GmbH
Authorised Representative Address:	Schiffgraben 41 30175 Hannover, Germany
Authorised Representative's SRN:	DE-AR-000005430

Product Name(s):	Dexcom G7 Continuous Glucose Monitoring System
Product Type:	Active Medical Device, Continuous Glucose Monitor
Intended Purpose:	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.
Basic UDI-DI:	038627G7CGM2Y
EMDN:	Z12040115
GMDN:	44611

Applicable Regulation/Directive(s):
The above-mentioned product is in conformity with the following legislative acts:

- Regulation (EU) 2017/745 on medical devices
- Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Regulation (EU) 2017/745 on medical devices	
Classification:	Class IIb, Rule 8 according to Annex VIII of Regulation (EU) 2017/745
Notified Body:	BSI Group The Netherlands B.V.
Notified Body Address:	Say Building, John M. Keynesplein 9 1066 EP Amsterdam, Netherlands
Notified Body ID#:	2797
Conformity Assessment:	Annex IX Chapters I and III
EC Certificate:	MDR 727974

6340 Sequence Drive
San Diego, CA 92121
www.dexcom.com

Radio Equipment Directive 2014/53/EU	
Harmonised Standard	IEC 60601-1:/AMD1 :2012 ETSI EN 301 489-1 V.2.2.3 (2019-11) ETSI EN 301 489-17 (2017-03) IEC 60601-1-2 (2014) ETSI EN 300 328 V2.2.2 (2019-07)

Restriction of Hazardous Substances Directive 2011/65/EU	
Harmonised Standard	EN IEC 63000:2018

Applicable Common Specifications:
There are no relevant common specifications for the above-mentioned products.

We, the undersigned, hereby declare that the products specified above conforms to the above Standards.

The EU declaration of conformity is issued under the sole responsibility of Dexcom Inc. as manufacturer and the device is in conformity with Regulation (EU) 2017/745 on medical devices.

Manufacturer: Dexcom, Inc.

I hereby declare that the products named above has been designed to comply with the relevant sections of Regulation (EU) 2017/745 on medical devices and the applicable Union legislative acts specified above. I hereby declare that the products are manufactured in conformity with the technical documentation referred to in Annex II and Annex III and meet the requirements of this Regulation which apply to them. The product complies with all general safety and performance requirements of the Regulation. All supporting documentation is retained under the premises of the manufacturer.

Signature: Neeta Sharma Digitally signed by Neeta Sharma Date: 2022.04.06 15:34:09 -07'00' for and on behalf of Dexcom Inc.

Date: _____

Full Name: Neeta Sharma
Position: Vice President, Regulatory Affairs
Place, Date of Issue: San Diego, April 6, 2022

Start of CE-Marking: March 11, 2022

6340 Sequence Drive
San Diego, CA 92121
1-858-200-0203
Fax 1-858-332-0204
www.dexcom.com

EU DECLARATION OF CONFORMITY
Radio Equipment Directive

Manufacturer's Name: DexCom, Inc.

Manufacturer's Address: 6340 Sequence Drive
San Diego, CA 92121
United States of America

Product Model/Name(s):

- STP-DO-(001 to 015)/ mg/dL, Dexcom ONE Starter Kit
- STP-DO-(101 to 115)/ mmol/L, Dexcom ONE Starter Kit
- STT-DO-(001 to 010)/ Dexcom ONE Transmitter
- STS-DO-(001 to 015)/ Dexcom ONE Sensor
- STK-DO-(001 to 015)/ mg/dL, Dexcom ONE Receiver
- STK-DO-(101 to 115)/ mmol/L, Dexcom ONE Receiver

Devices Comply with:

Frequency Band: 2402 – 2480 MHz
Output Power: -1.7dBm

The equipment described above is in conformity with the Directive 2014/53/EU, in accordance with the following harmonized standards:

Essential Requirements	Compliance Standard
Article 3(1)(a) Safety	EN 60601-1:2006/AMD1:2013
Article 3(1)(b) EMC	ETSI EN 301 489-1 V2.2.3 (2019-11), ETSI EN 301 489-17 (2017-03), EN 60601-1-2:2015
Article 3(2) Radio Spectrum Usage	ETSI EN 300 328 V2.2.2 (2019-07)
Article 3(3)	N/A, No delegated acts currently in force for radio equipment listed in this Declaration.

This document is valid until the date of the certificate expiration of May 26th, 2024 unless superseded by a more recent revision.

We, the undersigned, hereby declare that the equipment specified above conforms to the above Standards.

Signature: _____ Date: 16FEB2022

Full Name: Chris Cuddy Position: Director Quality Assurance, Dexcom Inc.

6340 Sequence Drive
San Diego, CA 92121
1-858-200-0203
Fax 1-858-332-0204
www.dexcom.com

EU DECLARATION OF CONFORMITY
RoHS Directive

Manufacturer's Name: DexCom, Inc.

Manufacturer's Address: 6340 Sequence Drive
San Diego, CA 92121
United States of America

Product Model/Name(s):

- STP-DO-(001 to 015)/ mg/dL, Dexcom ONE Starter Kit
- STP-DO-(101 to 115)/ mmol/L, Dexcom ONE Starter Kit
- STT-DO-(001 to 010)/ Dexcom ONE Transmitter
- STS-DO-(001 to 015)/ Dexcom ONE Sensor
- STK-DO-(001 to 015)/ mg/dL, Dexcom ONE Receiver
- STK-DO-(101 to 115)/ mmol/L, Dexcom ONE Receiver

Directive: Restriction on the use of certain Hazardous Substances (RoHS)

Devices Comply with:

EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

This document is valid until the date of the certificate expiration of May 26th, 2024 unless superseded by a more recent revision.

We, the undersigned, hereby declare that the equipment specified above conforms to the above Standards.

Signature: _____ Date: 16FEB2022

Full Name: Chris Cuddy Position: Director Quality Assurance, Dexcom Inc.