



PROTOCOL

FT-010012

Rev: 02

Declaration of Conformity Form

DOCUMENT OWNER: **Regulatory Affairs**

DECLARATION OF CONFORMITY FORM



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EC DECLARATION OF CONFORMITY

Manufacturer's Name: Dexcom, Inc.

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

Representative's Name: MediTech Strategic Consultants B.V.

Representative's Address: Maastrichterlaan 127-129
NL – 6291 EN Vaals
Tel. +31.43.306.3320
Fax +31.43.306.3338

Responsible Person: Andrew Balo, Executive Vice President of Regulatory, Clinical and Quality

Product Type: Active Medical Device, Continuous Glucose Monitor

Product: Dexcom G4 PLATINUM Continuous Glucose Monitoring System [Interstitial Fluid]

• **Model No(range)/Name.:**

- STK- GL -(001 to 099)/ mg/dL, Dexcom G4 PLATINUM Receiver Kit
- STK- GL -(101 to 199)/ mmol/L, Dexcom G4 PLATINUM Receiver Kit
- STR- GL -(002 to 099)/ mg/dL, Dexcom G4 PLATINUM Replacement Receiver Kit
- STR- GL -(101 to 199)/ mmol/L, Dexcom G4 PLATINUM Replacement Receiver Kit
- STT- GL -(001 to 010)/ Dexcom G4 PLATINUM Transmitter Kit
- STS- GL -(001 to 144)/ Dexcom G4 PLATINUM Sensor
- MT21190/Dexcom Studio

GMDN: P44611

Classification:

Sensor: Class IIb, Rule 8 according to Annex IX of the MDD 93/42/EEC & 2007/47/EC

Transmitter: Class IIa, Rule 10 according to Annex IX of the MDD 93/42/EEC & 2007/47/EEC

Receiver: Class IIb, Rule 10 according to Annex IX of the MDD 93/42/EEC & 2007/47/EC

Dexcom G4 Platinum System: Class IIb, Rule 8 according to Annex IX of the MDD 93/42/EEC & 2007/47/EC

Year of Manufacture: Indicated on each device on the Serial Number and Certification Label



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Devices Comply with:

EN 980: 2008	Symbols for use in the labelling of medical devices
EN ISO 10993-1:2009/AC:2010	Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a Risk Management Process
EN ISO 10993-2:2006	Biological Evaluation of medical devices – Part 2: Animal Welfare Requirements
EN ISO 10993-3:2009	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2009	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization
EN ISO 10993-11:2009	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 11137-1:2006/AC:2013	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices Part 1: Requirements for Material, Sterile Barrier Systems, and Packaging Systems
EN ISO 11607-2:2006	Packaging for terminally sterilized Medical Devices – Part 2: Validation Requirements for forming, sealing and assembly processes.
EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of Medical Devices – Microbiological Methods - Part 2: Tests of Sterility performed in the definition of a sterilization process.
EN ISO 13485:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 14644-1:1999	Cleanrooms and associated controlled environments- Part 1: Classification of air cleanliness
EN ISO 14644-2:2000	Cleanrooms and associated controlled environments- Part 2: Specifications testing and monitoring to prove continued compliance with ISO 14644-1
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments- Part 3: Test methods
EN ISO 14644-4:2001	Cleanrooms and associated controlled environments- Part 4: Design, construction and start-up
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments- Biocontamination control- Part 1: General principles and methods
EN ISO 14937:2009	Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
ISO 15223-1:2012	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied



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EN 62304:2006/AC: 2008	Medical Device Software - Software Life Cycle Processes
EN 62366:2008	Medical Devices – Application of Usability Engineering to Medical Devices
EN 60529:1991/A2:2013	Degrees of Protection Provided by Enclosures (IP code)
EN 60601-1:2007/A1:2010	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2007/AC:2014	Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010	Medical Electrical Equipment – Part 1-6 – General requirements for basic safety and essential performance - Collateral Standard: Usability
EN 60601-1-8:2007	Medical Electrical Equipment -Part 1-8 -Collateral Standard: General Requirements for basic safety and essential performance- Collateral Standard: General requirements, tests and guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
EN 60601-1-11:2010	Medical Electrical Equipment – Part 1-11 – General requirements for basic safety and essential performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment
EN 300 440-2 V1.4.1 (2002-08)	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Short Range Devices; Radio Equipment to be used in the 1 GHz to 40 GHz Frequency Range: Part 1: Technical Characteristics and Test Methods
EN 301 489-1 B.1.8.1 (2008-04)	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements
EN 300 489-1 V.1.4.1 (2002-08)	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements



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Notified Body: British Standards Institution (BSI)
Notified Body Address: Kitemark Court, Davy Avenue
Knowlhill, Milton Keynes, MK5 8PP, United Kingdom

Notified Body ID#: 0086

EC Certificates: CE 591560, FM 591535

Start of CE-Marking: Sensor STS-7CE-051; Lot 333351, 10/25/2012

Place, Date of Issue: San Diego, California, USA; 06 September 2012

Specific Applicable Directives

- * Radio and Telecommunications Terminal Equipment (R&TTE) Directive 1999/5/EC
- * Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS II)
- * Radio Equipment Directive (RED) 2014/53/EU

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

Manufacturer: Dexcom, Inc.

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the Council Directive 93/42/EEC and 2007/47/EC for medical devices. I hereby declare that the products are manufactured in conformity with the technical documentation referred to in Section 3 of Annex II and meet the requirements of this Directive which apply to them. The product complies with all essential requirements of the Directives. All supporting documentation is retained under the premises of the manufacturer

Signature: Andy Balo

Date: 6-6-2017

Full Name: Andy Balo Position: Executive Vice President, Clinical, Regulatory, and Global Access

CE 0086



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San Diego, CA 92121
United States of America**Representative's Name:** MediTech Strategic Consultants B.V.**Representative's Address:** Maastrichterlaan 127-129
NL – 6291 EN Vaals
Tel. +31.43.306.3320
Fax +31.43.306.3338**Responsible Person:** Andrew Balo, Executive Vice President of Regulatory, Clinical and Quality**Product Type:** Active Medical Device, Continuous Glucose Monitor**Product:** Dexcom G5 Mobile Continuous Glucose Monitoring System [Interstitial Fluid]

- **Model No(range)/Name.:**

- STK- GF -(001 to 099)/ mg/dL, Dexcom G5 Mobile Receiver Kit
- STK- GF -(101 to 199)/ mmol/L, Dexcom G5 Mobile Receiver Kit
- STR- GF -(002 to 099)/ mg/dL, Dexcom G5 Mobile Replacement Receiver Kit
- STR- GF -(101 to 199)/ mmol/L, Dexcom G5 Mobile Replacement Receiver Kit
- STT- GF -(001 to 010)/ Dexcom G5 Mobile Transmitter Kit
- STS- GF -(001 to 144)/ Dexcom G5 Mobile Sensor
- SW10841 G5 OUS Mobile iOS CGM App (mg/dL)
- SW10842 G5 OUS Mobile iOS CGM App (mmol/L)
- SW11170 G5 OUS App mg/dL for Android
- SW11171 G5 CGM OUS App mmol/L for Android
- SW10846 Dexcom Follow App for iOS (mg/dL)
- SW10847 Dexcom Follow App for iOS (mmol/L)
- SW10920 OUS Dexcom Follow App for Android (mg/dL)
- SW10930 OUS Dexcom Follow App for Android (mmol/L)

GMDN: P44611

Classification:**Sensor:** Class IIb, Rule 8 according to Annex IX of the MDD 93/42/EEC & 2007/47/EC**Transmitter:** Class IIa, Rule 10 according to Annex IX of the MDD 93/42/EEC & 2007/47/EC**Receiver:** Class IIb, Rule 10 according to Annex IX of the MDD 93/42/EEC & 2007/47/EC**Dexcom G5 Mobile System:** Class IIb, Rule 8 according to Annex IX of the MDD 93/42/EEC & 2007/47/EC**Dexcom G5Apps (G5 Mobile and Follow):** Class IIb, Rule 10 according to Annex IX of the MDD 93/42/EEC & 2007/47/EC**Year of Manufacture:** Indicated on each device on the Serial Number and Certification Label

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LBL015291 Rev 001



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EN 55011:2009+A1:2010	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement
EN 62304:2006/AC: 2008	Medical Device Software - Software Life Cycle Processes
IEC 62366:2008	Medical Devices – Application of Usability Engineering to Medical Devices
EN 60529:1991/A2:2013	Degrees of Protection Provided by Enclosures (IP code)
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IEC 60601-1-2:2014	Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010	Medical Electrical Equipment – Part 1-6 – General requirements for basic safety and essential performance - Collateral Standard: Usability
EN 60601-1-11:2010	Medical Electrical Equipment – Part 1-11 – General requirements for basic safety and essential performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment
EN 60068-2-27:2009	Environmental Testing – Part 2-27: Tests – Test EA and Guidance: Shock
IEC 60068-2-64: 2008	Environmental Testing – Part 2-64 : Tests – Test FH : Vibration, Broadband Random and Guidance
ISO 16269-6:2014	Statistical Interpretation of Data Part 6: Determination of Statistical Tolerance Intervals
ISO 7010:2012	Graphical symbols - Safety colours and safety signs - Registered safety signs
ISO 8573-1:2010	Compressed Air Part 1: Contaminants and Purity Classes
CLSI POCT05-A: 2008	Performance Metrics for Continuous Interstitial Glucose Monitoring: Approved Guideline
RTCA DO-160G:	Environmental Conditions and Test Procedures for Airborne Equipment
ETSI EN 301 489-1 V1.9.2 (2011-09)	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements
ETSI EN 301 489-3 V1.6.1 (2013-08)	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility V1.6.1
ETSI EN 301 489-17 V2.2.1 (2012-09)	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility V2.2.1
ETSI EN 300 328 V1.8.1 (2012-06)	Electromagnetic Compatibility and Radio Spectrum Matters, Short Range Devices Radio Equipment V1.8.1
ISTA 2A: 2011	Partial Series Simulation Performance Test Procedure
ASTM D4169-09	Standard Practice for Performance Testing of Shipping Containers and Systems
Cybersecurity	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff, Issued October 2014.



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Signature: 

Date: 6-6-2017

Full Name: Andy Balo Position: Executive Vice President, Clinical, Regulatory, and Global Access

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