DECLARATION OF CONFORMITY FORM
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:
    o STK- GL -(001 to 099)/ mg/dL, Dexcom G4 PLATINUM Receiver Kit
    o STK- GL -(101 to 199)/ mmol/L, Dexcom G4 PLATINUM Receiver Kit
    o STR- GL -(002 to 099)/ mg/dL, Dexcom G4 PLATINUM Replacement Receiver Kit
    o STR- GL -(101 to 199)/ mmol/L, Dexcom G4 PLATINUM Replacement Receiver Kit
    o STT- GL -(001 to 010)/ Dexcom G4 PLATINUM Transmitter Kit
    o STS- GL -(001 to 144)/ Dexcom G4 PLATINUM Sensor
    o 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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LBL015291 Rev 001
Devices Comply with:

EN 980: 2008 Symbols for use in the labelling of medical devices


EN ISO 10993-10:2013 Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization


EN ISO 13485:2012 Medical devices – Quality management systems – Requirements for regulatory purposes


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 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
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 60601-1-6:2010 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
declare of conformity form

Notified Body: British Standards Institution (BSI)
Notified Body Address: Kitemark Court, Davy Avenue
Knowhill, 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

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: [Signature] Date: 6-6-2017

Full Name: Andy Balo Position: Executive Vice President, Clinical, Regulatory, and Global Access
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.
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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:
  o STK- GF -(001 to 099)/ mg/dL, Dexcom G5 Mobile Receiver Kit
  o STK- GF -(101 to 199)/ mmol/L, Dexcom G5 Mobile Receiver Kit
  o STR- GF -(002 to 099)/ mg/dL, Dexcom G5 Mobile Replacement Receiver Kit
  o STR- GF -(101 to 199)/ mmol/L, Dexcom G5 Mobile Replacement Receiver Kit
  o STT- GF -(001 to 010)/ Dexcom G5 Mobile Transmitter Kit
  o STS- GF -(001 to 144)/ Dexcom G5 Mobile Sensor
  o SW10841 G5 OUS Mobile iOS CGM App (mg/dL)
  o SW10842 G5 OUS Mobile iOS CGM App (mmol/L)
  o SW11170 G5 OUS App mg/dL for Android
  o SW11171 G5 CGM OUS App mmol/L for Android
  o SW10846 Dexcom Follow App for iOS (mg/dL)
  o SW10847 Dexcom Follow App for iOS (mmol/L)
  o SW10920 OUS Dexcom Follow App for Android (mg/dL)
  o 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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Devices Comply with:

- EN 980: 2008 Symbols for use in the labelling of medical devices
- EN ISO 10993-10:2013 Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization
- EN ISO 13485:2012 Medical devices – Quality management systems – Requirements for regulatory purposes
- 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 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


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)


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


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


RTCA DO-160G:Environmental Conditions and Test Procedures for Airborne Equipment


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


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.
Notified Body: British Standards Institution (BSI)
Notified Body Address: Kitemark Court, Davy Avenue
Knowhill, 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 2014

Specific Applicable Directives

  Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS II)

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
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