



PROTOCOL

FT-010012

Rev: 02

Declaration of Conformity Form

DOCUMENT OWNER: Regulatory Affairs

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)
EN 60601-1:2006/A1:2013	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
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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LBL015291 Rev 001



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DOCUMENT OWNER: Regulatory Affairs

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 2014

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: 

Date: 6-6-2017

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

CE 0086