RED Declaration of Conformity
Radio Equipment Directive

Name and Address of Manufacturer:

WaveForm Technologies Inc.
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Salem, NH 03079
USA

EU Authorized Representative

MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Medical Device

Cascade Continuous Glucose Monitoring System (Cascade CGM and GlucoMen Day CGM)

GMDN Code – 44611

Risk Classification

The Cascade Continuous Glucose Monitoring (CGM) System is classified as a Class IIb medical device according to Rule 8, Annex IX of Medical Device Directive MDD 93/42/EEC.

Standards Applied

Safety (Article 3.1 a)	IEC 60601-1:2005+AMD1:2012; IEC 60601-1-2:2014; IEC 60601-1-11:2015
Electromagnetic Compliance (EMC) (Article 3.1 b)	EN 301 489-1 v.2.1.1; EN 301 489-17 V3.1.1; IEC 61000-4-2:2008; IEC 61000-4-3:2006+AMD1:2007+AMD2:2010; IEC 61000-4-4:2012; IEC 61000-4-5:2014+AMD1:2017 CSV; BS EN 61000-4-6:2014; BS EN 61000-4-11:2004; IEC 61000-6-1:2016; CISPR 11: 2015+AMD1:2016; BS EN 55011:2009 + A1:2010
Electromagnetic compatibility and Radio Spectrum Matters (ERM)	EN 300 328 v2.1.1

WaveForm Technologies hereby states that the Cascade Continuous Glucose Monitoring (CGM) System described above is in conformity with Radio Equipment Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014, when used for its intended purpose.

Authorized Signatory

Mihailo Rebec — 13 Dec 2019

Dr. Mihailo Rebec, Ph.D.
Chief Technology Officer

Date