EC DECLARATION OF CONFORMITY

Product name: *Sooma tDCS*
(REF: Sooma tDCS)

Manufacturer: *Sooma Oy*
Kuortaneenkatu 2
00510, Helsinki
Finland

Classification (MDD, Annex IX): *Class IIa product*
Rule 9 in Annex IX of the MDD 93/42/EEC

Indication for use Treatment of major depressive disorder and treatment of chronic neuropathic and fibromyalgia related pain

Directives:
93/42/EEC Medical Device Directive, amended by 2007/47/EC
629/2010 Laki terveydenhuollon laitteista ja tarvikkeista

Standards:

IEC60601-1:2005 + Corr. 1 (2006) + Corr. 2 (2007) + AM1 (2012)	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance IEC 60601-1:2005/A1:2012
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests IEC 60601-1-2:2014
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 60601-1-6:2010
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 IEC 60601-1-11:2010
EN 62366:2008	Medical devices - Application of usability engineering to medical devices IEC 62366:2007
EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes IEC 62304:2006
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN 1041:2008	Information supplied by the manufacturer of medical devices

Notified Body:	*SGS Fimko Oy, NB 0598* *Särkiniementie 3* *00210, Helsinki* *Finland*
Certificates:	Quality system according to ISO13485

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Place, Date:	Helsinki, 2019-10-03
Signature:	
Name:	Tuomas Neuvonen
Position:	CEO