



Manufacturer: Sooma Oy
Kuortaneenkatu 2
00510, Helsinki
FINLAND

Products: Sooma tDCS accessories:

REF	Product
EL55	tDCS electrode, 50x50 mm
ELM1	tDCS electrode, 100x50 mm + 50x70 mm
ELM2	tDCS electrode, 50x70 mm
CE25	ComfoTrode -electrode
CSNP	ComfoLeads -cables
CP25	ComfoPad -conductive pad, 25 cm ²
CCx0 (XS, S, M, L)	ComfoCap -headgear, M0, sizes XS, S, M, L
CCx2 (XS, S, M, L)	ComfoCap -headgear M2, sizes XS, S, M, L
CCx3 (XS, S, M, L)	ComfoCap -headgear M3, sizes XS, S, M, L
SCx2 (S, M, L)	Smart Cap -headgear, M2, sizes XS, S, M, L
HM2x (S, M, L)	Flex Cap -headgear, M2, sizes S, M, L
HM3x (S, M, L)	Flex Cap -headgear, M3, sizes S, M, L
SP55	tDCS electrode sponge, 50x50 mm
SPM1	tDCS electrode sponge, 100x50 mm + 50x70 mm
SPM2	tDCS electrode sponge 50x70 mm

Classification (MDD, Annex IX):

Class I
Rule 1, Annex IX, MDD 93/42/EEC

Product meets the provisions of the following directives:

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

EC DECLARATION OF CONFORMITY



Product meets the provisions of the following standards:

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)

Notified Body:

*SGS Fimko Oy, NB 0598
Särkiniementie 3
00210, Helsinki
FINLAND*

Certificates:

Quality Management system according to ISO 13485:2016

We hereby declare that the above-mentioned product meet the provisions of the Council Directives and Standards listed in this declaration. All supporting documentation are retained under the premises of the manufacturer.

Place, date:

Helsinki, 2019-09-30

Signature:

A handwritten signature in blue ink, appearing to read "Tuomas Neuvonen", is written over a horizontal line. A blue watermark of the Sooma logo is oriented diagonally across the signature.

**Name:
Position:**

Tuomas Neuvonen
CEO