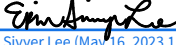


MANUFACTURER'S EU DECLARATION OF CONFORMITY

1	MANUFACTURER'S NAME	Flow Neuroscience AB
2	WEBSITE	https://flowneuroscience.com
3	BUSINESS ADDRESS	Södra Tullgatan 3, 211 40, Malmö, Sweden
4	MEDICAL DEVICE(S)	Flow FL-100
5	DEVICE CLASSIFICATION	Class IIa
6	SCOPE OF APPLICATION	Transcranial Direct Current stimulators (tDCS) and associated software applications for treatment of mental and neurological disorders (Depression).
7	QMS CERTIFICATE	MD 673332 (ISO 13485:2016 & EN ISO 13485:2016)
8	DECLARATION	Hereby Fow Neuroscience AB declares that the Flow FL-100 device meets the requirements of: <ul style="list-style-type: none">- European conformity assessment certificate under Annex II 3.2, of Council Directive 93/42/EEC on Medical Devices as Amended by 2007/47/EC.
9	EC CERTIFICATE	CE 673331
10	NOTIFIED BODY	BSI (2797) The Netherlands; Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
11	ROHS:	RoHS Dir 2011/65/EU of 8 June 2011
12	BASIC UDI-DI	731458FL-100RN
13	EMDN	N0199
14	SRN	SE-MF-000018547
15	DATE	2023-05-10
16	AUTHORIZED SIGNATORY	Erin Lee (CEO)  <small>Erin Sivyler Lee (May 16, 2023 15:07 GMT+1)</small>

#	APPLIED COMMON SPECIFICATIONS & STANDARDS	
1	EN ISO 13485:2016 (ISO 13485:2016)	Medical devices Quality Management Systems Requirements for regulatory purposes
2	EN ISO 14971:2019 (ISO 14971:2019)	Application of Risk Management to Medical Devices
3	EN 62304:2006/AC:2008/A1:2015 (IEC 62304:2015)	Medical Device Software - Software Life Cycle
4	EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)	Medical electrical equipment - Part 1: General requirements or basic safety and essential performance
5	EN 60601-1-2:2015 (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
6	EN ISO 15223-1:2016	Symbols for use in the labeling of medical devices
7	SS-EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
8	EN 60601-1-11:2015 (IEC 60601-1-11:2015)	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
9	EN ISO 10993-1:2009/AC:2010 (ISO 10993-1:2009)	Biological evaluation of medical devices - Part 1: Evaluation & testing within a risk management process
10	IEC TR 62366-2; 2016 (IEC 62366:2015)	Medical devices - Part 1: Application of usability engineering to medical devices
11	EN 62133-2: 2017+A1	Safety Test Std- Recharge Li-ion Polymer Battery (LiPo)

END OF DOCUMENT







GR 18-148 EU DoC - Flow FL-100 ver07A

Final Audit Report

2023-05-16

Created:	2023-05-16
By:	Johan Olsson (johan@flowneuroscience.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAul6RYcG0tpdGWoL7XhLtVUUstJlSHfAL

"GR 18-148 EU DoC - Flow FL-100 ver07A" History

-  Document created by Johan Olsson (johan@flowneuroscience.com)
2023-05-16 - 1:52:43 PM GMT
-  Document emailed to erin@flowneuroscience.com for signature
2023-05-16 - 1:53:06 PM GMT
-  Email viewed by erin@flowneuroscience.com
2023-05-16 - 1:54:16 PM GMT
-  Signer erin@flowneuroscience.com entered name at signing as Erin Sivyler Lee
2023-05-16 - 2:07:20 PM GMT
-  Document e-signed by Erin Sivyler Lee (erin@flowneuroscience.com)
Signature Date: 2023-05-16 - 2:07:22 PM GMT - Time Source: server
-  Agreement completed.
2023-05-16 - 2:07:22 PM GMT

