



CE / ISO13485 DECLARATION OF CONFORMITY

Manufactures Name: A-1 Engineering
Brand Names: NeurotriS SX / SVX Series
Manufactures Address: 30 Mauchly Suite A
Irvine, California 92618 USA
Devices: NeurotriS SX Series Machines
Intended Use: Intended for muscle conditioning to stimulate healthy muscles.
Classification: Regulatory Class II, 21 CFR 890.5850
Voltage Rating: 110 – 240vac 50 – 60 Hz 2A
Product Code : FDA 510K Cleared K182440 / NGX
Scope of Application SX / SVX Series Machines
MRA Conformity Assessment Body: CSA International



CSA INTERNATIONAL

MRA Certified Body Testing Facility

Referenced Safety Standard

Standard IEC 60601-1: 2005 / (R) 2012 + A1; 2012. MOD CE
Test Procedure CE Scheme
Test Report Form # IEC 60601_1G
Report Form Originator Underwriters Laboratory Inc.

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The units comply with all applicable Essential Principals and Requirements of the Directive and have been inspected / tested by an authorized MRA body testing facility CSA International. A-1 Engineering is a California USA Department Public Health (CDPH) FDA approved licensed medical device ISO 13485 manufacture certificate License # 78634 that meets and exceeds quality manufacturing standards for safety, performance & Validation.

Authorized Manufacture Representative:

Anthony Picciano Owner

Irvine, California USA



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Document Ref. No:

100-2015-11

November 1st 2017