DECLARATION OF CONFORMITY
FDA 510K CLEARED
EN ISO 13485-2016
IN ACCORDANCE WITH QSR FDA 21 CFR PART 820

Manufactures Name:	A-1 Engineering
Brand Name:	NeurotriS
Manufactures Address:	30 Mauchly Suite A Irvine, California 92618 USA
Medical Devices:	SX Series Machines
Intended Use:	Facial & Body Sculpting
FDA 510K Cleared:	K182440
Validation:	Product Claims Validation
FDA Code:	NGX
Scope of Application	ISO 13485-2016 Compliance

Independent Certification Auditor: MasterControl

Referenced Specifications

Scope:	FDA, CE, ISO 13485, ISO 14971 Compliance Consulting
Procedure:	Internal Audit
Audit Report Form #:	QP802 / FM802
Audit Originator:	Walt Murry ARC Experts

I hereby declare that the manufacturer named above has been certified to comply with the relevant sections of the above referenced specifications. The manufacture complies with all applicable Essential Principals and Requirements of the QSR FDA 21 CFR Part 820 and ISO 13485-2016 and has been inspected / audited by an independent FDA certification body *Master Control*. A-1 Engineering is a California USA Department Public Health (CDPH) approved licensed medical device manufacture certificate License # 78634 that meets and exceeds ISO 13485-2016 quality manufacturing standards for Quality, Safety, Performance and Validation Testing.

Authorized Manufacture Representative:

Anthony Picciano CEO
Irvine, California USA

13485:2016 Certified

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January 1st 2017