

ELECTRICAL LISTING PROGRAM

Customer: Navigate Surgical Technologies Inc.
 Class: Medical Electrical Equipment
 Location: Vancouver, BC, Canada
 Listing No. E10597
 Report No. E10597-1901
 Project No. E10597-1901
 Effective Date: 2019-08-29
 Last Revised Date: 2019-08-29
 Expires: N/A

Standards: CAN/CSA-C22.2 No. 60601-1
 CAN/CSA-C22.2 No. 60601-1-6

Product: Surgical Navigation System, Medical Electrical Equipment, Class I, cord-set connected, mobile, no patient applied parts

Markings: Products are marked in a permanent manner where it is readily visible after installation with the following:

- a) Manufacturer’s name or trademark.
- b) Model number or designation.
- c) Electrical ratings: voltage, frequency, input.
- d) Month and year of manufacture. Date coding, serial number or equivalent means may be used.
- e) QAI Listing Mark:



- f) QAI Listing Number: E10597.
- g) The statement “Conforms to CSA 60601-1”.
- h) Type and full rating of mains fuses.

Models / Ratings:

Model	Rating
Inliant 900027	100-240 Vac, 50/60 Hz, 140 VA

- Notes:
1. Requirements for biocompatibility (Subclause 11.7) and electromagnetic compatibility (Clause 17) are not evaluated (N/E) in this evaluation. Consideration shall be made by the Manufacturer in the end use.
 2. Hazards resulting from intended physiological effects or from the abnormal use of the Product are not considered in this evaluation.
 3. The Manufacturer’s risk management file for the Product is reviewed in accordance with the requirements of ISO 14971 as part of this evaluation. The Manufacturer’s risk management decisions inform the

- applicable test and evaluation requirements. The Manufacturer shall notify QAI of any changes or revisions in the risk management file that affect the compliance of the Product with the applicable Standards.
4. If this Product is subsequently combined with other equipment through a functional connection or by use of a multiple socket-outlet, consideration of the requirements of Clause 16 for Medical Electrical Systems shall be made by the Manufacturer or the Responsible Organization in the end use.

The materials, products or systems listed herein have been qualified to bear the QAI Listing Mark under the conditions stated with each Listing. Only those products bearing the QAI Listing Mark are considered to be listed by QAI. No warrantee is expressed or implied, and no guarantee is provided that any jurisdictional authority will accept the Listing found herein. The appropriate authorities should be contacted regarding the acceptability of any given Listing. Visit the QAI Online Listing Directory located at www.qai.org for the most up to date version of this Listing and to validate that this QAI Listing is active. Questions regarding this listing may be directed to info@qai.org. Please include the listing number in the request.
