QAI LABORATORIES
CERTIFICATION TESTING INSPECTION

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ELECTRICAL LISTING PROGRAM

Customer:	Navigate Surgical Technologies Inc.
Class:	Medical Electrical Equipment
Location:	Vancouver, BC, Canada
Listing No.	E10597
Report No.	E10597-1901, Ed.2
Project No.	E10597-2101
Effective Date:	August 08, 2019
Last Revised Date:	April 27, 2021
Expires:	N/A
Standards:	CAN/CSA-C22.2 No. 60601-1 ANSI/AAMI ES60601-1
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 C22.2#60601-1" (cQAI).
h) The statement "Conforms to AAMI ES60601-1" (QAIus)
i) Type and full rating of mains fuses.

Models / Ratings:

Model	Rating	Description	Environmental Locations
900027-0	100-240 Vac, 50/60 Hz, 140 VA	Surgical Navigation System for Canadian market (cQAI).	Dry location only
900010-1	100-240 Vac, 50/60 Hz, 140 VA	Surgical Navigation System for US market (QAIus)	Dry location only

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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.

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