

VANCOUVER, BC: LOS ANGELES, CA: TULSA, OK: TORONTO, ON WEBSITE:

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ELECTRICAL LISTING PROGRAM

Customor	Navigate Surgical Technologies Inc.		
	Medical Electrical Equipment		
	Vancouver, BC, Canada		
Listing No.			
•	E10597 E10597-1901, Ed.2		
	E10597-2101		
	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) QALListing Mark		

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" (QAlus)
- 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 (QAlus)	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.

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 <u>www.qai.org</u> 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 <u>info@qai.org</u>. Please include the listing number in the request.
