Certificate of Compliance

Certificate: 80008578 **Master Contract:** 180133

Project: **80008578** **Date Issued:** March 17, 2020

Issued to: **steute Technologies GmbH & Co. KG**
Brueckenstrasse 91,
32584 Loehne Germany

Attention: Mr. Partick Ye

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US or with adjacent indicator 'US' for US only or without either indicator for Canada only

Issued by: Alvin Kuang, PGM

PRODUCTS

CLASS 8780 01 - MEDICAL ELECTRICAL EQUIPMENT (Canadian adopted IEC 60601-1 3rd edition)
CLASS 8780 81 - MEDICAL ELECTRICAL EQUIPMENT (US Adopted IEC 60601-1 3rd edition)

Component type Medical footswitch, portable cord-connected,

Model:

Series:	(x): Switching function	Description:	(x***): Information e.g. customer
VKF 2 (x) – MED (x***)	1PW/D/1PW	1PW/D/1PW: 1 normally open contact + Pressure point switch fornormally open contact (Reed)	

2PW 1PW/D/1PW	2PW: 2 Change-over contact (Microswitch) 1PW/D/1PW: 1 normally open contact + Pressure point switch fornormally open contact (Reed)
1PW	Change-over contact (Microswitch)
2PW	2 Change-over contact (Microswitch)

Rated: Input: 60Vdc or 25Vac, 25W;

1. Medical device protection against electric shock: To be determined in end-product
2. Applied Part protection against electric shock: No applied part
3. Degree of protection against ingress of water or particulate matter: IPX8
4. Method of Sterilization: None
5. Suitability for use in an Oxygen Rich Environment: Medical device not intended to be used in an Oxygen Rich Environment
6. Suitability to use Medical device in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Medical device not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
7. Mode of operation: Continuous operation
8. Environmental Conditions: Normal: -10-40°C, 10-100% RH, 700-1060hPa.
   Transport and storage: -40°C to 70°C, 10-100% RH, 500-1060hPa.

Notes:

The above model has been evaluated as a component for a medical equipment where the suitability of the combination is to be determined in the end use application

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:14	CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)
CAN/CSA-C22.2 No. 60601-2-2:19	Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical accessories (Adopted IEC 60601-2-2, edition 6.0, 2017-03)

	Clause 201.8.10.4.101.4, 201.11.6.3 and 201.11.6.5 a) are applicable only
CAN/CSA-C22.2 No. 60601-2-22:08/AMD1	Medical electrical equipment - Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment (Adopted IEC 60601-2-22:2007 + A1:2012 – edition 3.1) Clause 201.8.10.4.101 is applicable only
CAN/CSA-C22.2 No. 60601-2-43:11+ AMD1: 2019	Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures – Consolidated Edition 2.1 Clause 201.11.6.5.101 and 201.11.6.5.103 are applicable only

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005/(R)2012, AND C1:2009 AND A2:2010(R)2012 (Consolidated text - edition 3.1)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD).
ANSI/AAMI/IEC 60601-2-2:2017	Medical electrical equipment - Part 2: General requirements for the basic safety and essential performance of high frequency surgical accessories Clause 201.8.10.4.101.4, 201.11.6.3 and 201.11.6.5 a) are applicable only
IEC 60601-2-22:2007 + A1:2012	Medical electrical equipment - Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment – Consolidated Edition 3.1 Clause 201.8.10.4.101 is applicable only
IEC 60601-2-43: 2010+ AMD1: 2017	Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures – Consolidated Edition 2.1 Clause 201.11.6.5.101 and 201.11.6.5.103 are applicable only

Reference standards

IEC 60601-1:2005 + Corr.1(2006) + Corr.2 (2007) + AM1 (2012)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Subject to the following qualifications:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND C1:2009 AND A2:2010(R)2012 excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7) and Usability (Clause 12.2). These exclusions shall be evaluated in the end product.

(2) Safety Risk Management: A risk management process complying with the requirements of standard ISO 14971 was inspected during the evaluation of this medical device and/or additional considerations were taken into account since the subject legacy medical device was evaluated to the previous edition of this standard. During the evaluation of this medical device, the risk management decisions affecting the test requirements have been taken into consideration. Changes/Updates in risk management documents that affect the safety of this medical device during its lifecycle shall be communicated to the CSA Group as a condition for continued certification.

(3) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

(4) Interconnection of this medical device with other medical devices, medical used systems or non-medical devices shall be evaluated to the requirements of Clause 16 in the end use application.

(5) Equipment needs to be re-evaluated in combination with end product.

(6) Steute provide information for the end product manufacturer. The end use manufacturer has to incorporate the necessary information within their user manual. Accompanying documents has to be evaluated with the end product.

(7) The subject models are evaluated only as components of other Medical equipment, where the suitability of the combination is to be determined by the Accepting NCB.

(8) The circuit isolation of two means of protection (2MOP) to the mains circuit shall be provided for footswitch in the end product. Footswitch evaluated for 2 MOOP for secondary voltage of 60V dc and 25V ac

(9) Connection and anchorage of a flexible cord of footswitches must fulfil the requirements for power supply cords in Cl. 8.11.3 at both ends of the cable to the end device.

(10) Risk Controls/Engineering Considerations for component footswitch:

For use only in or with complete equipment where the acceptability of the combination is to be determined by CSA Group, when installed in an end-product, consideration must be given to the following: End product Risk Management Process to include consideration of requirements specific to the footswitch. End product Risk Management Process to consider the need for simultaneous fault condition testing.

(11) Usability is not evaluated in this report and has to be evaluated in the end product.

(12) For particular standard IEC 60601-2-2:2017, only clause 201.8.10.4.101.4, 201.11.6.3 and 201.11.6.5 a) have been tested in this evaluation. Footswitch needs to be re-evaluated in combination with end product according to IEC 60601-2-2 standard

(13) For particular standard IEC 60601-2-22:2007+AMD1:2012, only clause 201.8.10.4.101 has been tested in this evaluation. Footswitch needs to be re-evaluated in combination with end product according to IEC 60601-2-22 standard.

(14) For particular standard IEC 60601-2-43:2010+AMD1:2017, only clause 201.11.6.5.101 and 201.11.6.5.103 have been tested in this evaluation. Footswitch needs to be re-evaluated in combination with end product according to IEC 60601-2-43 standard.

MARKINGS

The manufacturer is required to apply the following markings:

- Products shall be marked with the markings specified by the particular product standard.
- Products certified for Canada shall have all Caution and Warning markings in both English and French.

Additional bilingual markings not covered by the product standard(s) may be required by the Authorities Having Jurisdiction. It is the responsibility of the manufacturer to provide and apply these additional markings, where applicable, in accordance with the requirements of those authorities.

The products listed are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US (indicating that products have been manufactured to the requirements of both Canadian and U.S. Standards).

On the Equipment Exterior:
Equipment is plainly marked in a permanent manner in a place where the details will be readily visible after installation with the following:

- The CSA applicable mark / US / C US with optional reference to Standard, CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND c1:2009 AND a2:2010(r)2012 (for classes 8780-01 / 81)).
- Manufacturer's identification: Name and/or CSA file number on the same label as the CSA Mark. The name and/or trademark should appear elsewhere on the equipment if only the file number is used on this label.
- Catalogue/Model/Type designation.
- Date of manufacture: Month and year of manufacture or date code. If a serial number is used instead of date of manufacture, a record of serial numbers shall be kept traceable to date of manufacture. (Not related to date of sale).
- Complete electrical ratings; in volts (V), Watts (W).
- Protection against ingress protection according to IEC 60529, IPX8 rating.

Supplement to Certificate of Compliance

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The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.

Product Certification History

Project	Date	Description
80008578	**March 17, 2020**	**Original Certification.**