# Certificate of Compliance

**Certificate:** 70210440 **Master Contract:** 180133 (085005_0_000)

**Project:** 70210440 **Date Issued:** 2019-02-27

**Issued to:** **steute Technologies GmbH & Co. KG**
**Brueckenstrasse 91**
**Loehne, Nordrhein-Westfalen 32584**
**GERMANY**

**Attention: Patrick Keilwerth**

***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:** *Ronald Garcia*
Ronald Garcia

**PRODUCTS**

CLASS - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS-Certified to US Standards

Medical Electrical Component, cord-connected footswitches, Model/Type:

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| Series: | (x): Switching function | Description: | (x**): Baseplate | (x***): Information e.g. customer |
|---|---|---|---|---|
| (M)KF (x) – MED (x*) (x**) (x***) | 1S | Normally open contact (reed) | GP111 | |
| | 2S | 2 normally open contacts (reed or microswitch) | GP211 | |
| (M)KF 2 (x) – MED (x*) (x**) (x***) | 1W | Change-over contact (reed) | GP311 | |
| | 1PW | Change-over contact (microswitch) | GP411 | |
| | 2PW | 2 Change-over contact (microswitch) | | |
| (M)KF 3 (x) – MED (x*) (x**) (x***) | 1SD1S | 1 normally open contact + pressure point | | |
| | 2SD1Ö | 2 normally open contact (reed) + pressure point + 1 normally close contact (microswitch) | | |
| (M)KF 4 (x) – MED (x*) (x**) (x***) | D1S | Pressure point +1 normally open contact | | |
| | D2S | Pressure point +2 normally open contact | | |
| | HS | Hall sensor with analog output signal<br>0-3,3V<br>0-5 V<br>0,5-5 V<br>0-7,5 V<br>0-10 V<br>0-20mA<br>4-20mA<br>20-4mA | | |

**(x*) Special product information**

Cord-connected: Non-detachable cord, portable, rated: 25 V AC / 60 V DC.

1. Medical device protection against electric shock: -
2. Applied Part protection against electric shock: Not Classified
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
8. Environmental Conditions: Normal: -10 to +60 °C, 10 to 100 % RH, 800-1060hPa

## 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. 60601-2-2:09 (R2014) | Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (Adopted IEC 60601-2-2:2009, fifth edition, 2009-02)<br>Clause 201.8.10.4.101.4 and 201.11.6.5 a) are applicable only |
| CAN/CSA-C22.2 NO. 60601-2-22:08 + AMD1 | Medical Electrical Equipment part 2-22: 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 This consolidated version consists of the third edition (2007) and its amendment 1 (2012)).<br>Clause 201.8.10.4.101 is applicable only |
| CAN/CSA-C22.2 NO. 60601-2-43:11 | Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures (Adopted IEC 60601-2-43:2010, second edition, 2010-03)<br>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) | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance<br>(IEC 60601-1:2005+A1:2012,MOD) |
| ANSI/AAMI/IEC 60601-2-2:2017 | Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories<br>Clause 201.8.10.4.101.4 and 201.11.6.5 a) are applicable only |
| IEC 60601-2-22:2007 | Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment<br>Clause 201.8.10.4.101 is applicable only |
| IEC 60601-2-43:2000 | Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures<br>Clause 201.11.6.5.101 and 201.11.6.5.103 are applicable only |

**Subject to the following qualifications:**

1) Evaluated to IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012, excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7). These exclusions shall be evaluated in the end product/device.
2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
3) 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.
4) Equipment needs to be re-evaluated in combination with end product.
5) Steute provide information for the end product manufacturer. The end use manufacturer has to incorporate the necessary information within their user manual.
6) The end product manufacturer has to incorporate the footswitch and receiver in their risk and usability evaluation. Steute can support them with the footswitch related hazards.
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) CSA cannot be held liable or responsible for standards/clauses which were applicable to the product but were not mandated by the submitter to be evaluated by CSA. Refer to Summary of applicable standards/clauses to evaluated product.
9) 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
10) The circuit isolation of two means of protection (2 MOP) to the mains circuit shall be provided for footswitch in the end product.
11) 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.

**Technical Considerations:**

1. Scope of footswitch evaluation defers the following clauses to be determined as part of the end product investigation:

- Clause 7.4 (Marking of controls and instruments),
- Clause 7.5 (Safety Signs),
- Clause 7.9 (Accompanying Documents),
- Clause 8.7 (Leakage currents),
- Clause 8.4 (Limitation of voltage, current or energy),
- Clause 8.5 (Separation of parts),
- Clause 8.10.4 (Cord-connected hand-held parts and cord-connected foot-operated control devices)
- Clause 8.8.3 (Dielectric strength),
- Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,

- Clause 10 (Radiation),
- Clause 11.6 (Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME equipment),
- Clause 13 (Hazardous Situations and Fault Conditions),
- Clause 14 (PEMS),
- Clause 16 (ME Systems)

## 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) or with adjacent indicator 'US' for US only or without either indicator for Canada only.

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 / / with optional reference to Standard, CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2012 as per adopted IEC 60601-1:2012 3.1 edition
- 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).
- Protection against ingress protection according to IEC 60529, IPX8 for footswitches.
- Complete electrical ratings; in volts (V)

# *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 |
|---|---|---|
| 70210440 | 2019-02-27 | Initial cCSAus Certification of cord-connected footswitches MKF 2S-MED GP111, MKF 2 2S/2S-MED GP211, MKF 3 2S-MED GP311, MKF 4 2S-ME D GP411 according to 60601-1 Edition 3.1. |