Certificate of Compliance

Certificate: 2503504 **Master Contract:** 180133

Project: 80007964 **Date Issued:** 2020-02-10

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

Attention: Patrick Heubaum

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

C US

PRODUCTS

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

Footswitches for use with Medical Electrical Equipment / Medical Electrical System, cord-connected: Non-detachable cord, Transportable, Portable, Model/Type:

Series:

Medical footswitches

(M)KF (S) (x) - MED - (x*) (x) (x***)**
(M)KF 2 (S) (x)/(x) - MED - (x*) (x) (x***)**
(M)KF 3 (S) (x)/(x)/(x) - MED - (x*) (x) (x***)**
(M)KF 4 (S) (x) - MED - (x*) (x) (x***)**
(M)KF 5 (S) (x) - MED - (x*) (x) (x***)**

Medical multi-function footswitches

MFS (x) (x*) - MED - (x*) (x**)**
(M)GF (x) - MED - (x*) (x*)**
(M)GF 2 (x)/(x) - MED - (x*) (x*)**
MGFS (x)/(x)/(x) - MED – (x*) (x*)**

Medical rocker footswitches

WF (x)/(x) - MED - (x*) (x) (x***)**
WF 2 (x)/(x) - MED - (x*) (x) (x***)**
WF 3 (x)/(x)/(x) - MED - (x*) (x) (x***)**

Medical round footswitches

RF (x) - MED (x*) (x*) (x*)**

(x)	Switch function description	Electrical Ratings
1S	Normally open contact (Reed)	25 Vac / 60 Vdc. 1A
2S	2 Normally open contacts (reed or microswitch)	25 Vac / 60 Vdc. 1A
1W	Change-over contact (Reed)	25 Vac / 60 Vdc. 1A
2W	2 Change-over contact (Reed)	25 Vac / 60 Vdc. 5A
1PW	Change-over contact (Microswitch)	25 Vac / 60 Vdc. 5A
2PW	2 Change-over contact (Microswitch)	25 Vac / 60 Vdc. 5A
D1S	Pressure point switch for normally open contact (Reed)	25 Vac / 60 Vdc. 1A
D2S	Pressure point switch for 2 normally open contact (Reed or microswitch)	25 Vac / 60 Vdc. 1A
1SD1S	1 normally open contact + Pressure point switch for normally open contact (Reed)	25 Vac / 60 Vdc. 1A
2SD1S	2 normally open contact + Pressure point switch for normally open contact (Reed)	25 Vac / 60 Vdc. 1A
D2S / D2S	2 x 2 pressure point switches (two per pedal), each consisting of Normally open contacts (reed or microswitch)	25 Vac / 60 Vdc. 1A
1Ö / 1S	Switching element consisting of 1 normally closed + 1 normally open contact	25 Vac / 60 Vdc. 1A
2Ö / 2S	2 Switching elements consisting of 1 normally closed + 1 normally open contact	25 Vac / 60 Vdc. 1A
1ÖS / 1ÖS	2 Switching elements (one per pedal), each consisting of 1 normally closed + 1 normally open contact	25 Vac / 60 Vdc. 1A
2ÖS / 2ÖS	2 x 2 Switching elements (two per pedal), each consisting of 1 normally closed + 1 normally open contact	25 Vac / 60 Vdc. 1A
HS (0-3,3V)	Hall sensor with analog output signal 0-3,3V	Ue: 5 Vdc, max. 12V / 25 mA
HS (0-5 V)	Hall sensor with analog output signal 0-5 V	Ue: 15..30 Vdc / 25 mA
HS (0,5V-5V)	Hall sensor with analog output signal 0,5-5 V	Ue: 15..30 Vdc / 25 mA
HS (0-7,5V)	Hall sensor with analog output signal 0-7,5 V	Ue: 15..30 Vdc / 25 mA
HS (0-10 V)	Hall sensor with analog output signal 0-10 V	Ue: 15..30 Vdc / 25 mA
HS (0-20mA)	Hall sensor with analog output signal 0-20 mA	Ue.: 15..30 Vdc / 45 mA
HS (4-20mA)	Hall sensor with analog output signal 4-20 mA	Ue: 15..30 Vdc / 45 mA
HS (20-4mA)	Hall sensor with analog output signal 20-4 mA	Ue: 15..30 Vdc / 45 mA
HS (0-255mA)	Hall sensor with digital output signal 0-255	Ue: 5 Vdc
HS RS-485	Hall sensor with RS-485 output signal	Ue: 5Vdc / 200 mA
HS RF SW 2.4	Hallsensor with radio frequency 2,4GHz	Ubat: 3,6V / 2,25Ah
Poti	Potentiometer: 1K, 2K, 5K, 10K, 50K	

(x*)	Special product information
2G	Second generation for RF model
USB	USB Output

AP	Category AP for models MKF, MGF, WF and RF e.g. RF 1PW-MED-AP
HID	Human Interface Device (see description below)
SK11	Protective metal flap for models (M)KF
SK12	Protective PA6 flap for models (M)KF

HID (Human Interface Device)
steute HID solution is basically a PCB mounted in a plastic housing to fit into standard USB Type A connectors. It is Capable to connect up to four switching contacts or up to two analog signals. There are five different modes available, Keyboard, Generic, Virtual COM-Port, Joystick and Mouse. Each solution is configurable according to the customer's needs (e.g. scan codes for a keyboard, X and Y axis with different resolution for a analog joystick etc.). This functionality can be integrated into many different standard and/or customized base plates, depending on the customers' needs.

(x)**	Baseplate	
1- pedal		
GP 11	192 x 165 x 29 mm (BxTxH)	
GP 12	178 x 188 x 45 mm (BxTxH)	
GP 13	272 x 246 x 60 mm (BxTxH)	
GP 14	100 x 272 x 50 mm (BxTxH)	
GP 16	230 x 188 x 42 mm (BxTxH)	
GP 17	190 x 184 x 44 mm (BxTxH)	
GP 18	155 x 98 x 34 mm (BxTxH)	
2- pedal		
GP 21	352 x 195 x 45 mm (BxTxH)	
GP 22	352 x 195 x 45 mm (BxTxH)	
GP 23	256 x 182 x 46 mm (BxTxH)	
GP 24	256 x 182 x 46 mm (BxTxH)	
GP 25	213 x 108 x 39 mm (BxTxH)	
GP 26	340 x 186 x 65 mm (BxTxH)	
GP 28	256 x 182 x 46 mm (BxTxH)	
GP 29	256 x 182 x 46 mm (BxTxH)	
GP 212	357 x 190 x 66 mm (BxTxH)	
3- pedal		
GP 31	310 x 157 x 35 mm (BxTxH)	
GP 32	356 x 183 x 47 mm (BxTxH)	
GP 33	356 x 183 x 47 mm (BxTxH)	
GP 34	413 x 250 x 47 mm (BxTxH)	
GP 35	290 x 255 x 45 mm (BxTxH)	from extruded section GP 71
4- pedal		
GP 41	410 x 157 x 35 mm (BxTxH)	
GP 42	438 x 198 x 47 mm (BxTxH)	

GP 44	438 x 198 x 47 mm (BxTxH)
GP 45	647 x 253 x 50 mm (BxTxH)
GP 47	475 x 127 x 31 mm (BxTxH)
5- pedal	
GP 51	500 x 157 x 35 mm (BxTxH)
(x)- pedal	
GP 71	(extruded section)
GP712	332 x 219 x 46 mm (BxTxH)

(x*) information e.g. customer**

1. Medical device protection against electric shock: -
2. Applied Part protection against electric shock: No applied part
3. Degree of protection against ingress of water or particulate matter: IPX1 to 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 suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide (for category AP models only)
7. Mode of operation: Continuous
8. Environmental Conditions: Normal-10 - +60°C, 10-100%, 800-1060hPa, 700-1060hPa for MGF 2 model
9. Software / Revision: -

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) (excluding Models KF 2 1PW/1PW-MED on plastic console and RF2S-MED)
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 (07) Ed. 3) (excluding Model RF2S-MED)

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)

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 60601-2-2:2009	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 (excluding Models KF 2 1PW/1PW-MED on plastic console and RF2S-MED)
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 (excluding Model RF2S-MED)
IEC 60601-2-43:2000	Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures

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 (Consolidated text - edition 3.1), excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Usability (Clause 7.1.1 and 12.2), Biocompatibility (Clause 11.7), Risk management (ISO14971, Clause 4.2). 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 the end device. Technical Consideration shall be evaluated in end device.

(5) steute provides 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 in their risk 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) The circuit isolation of 2 MOP’s to the mains circuit have to be provided in the end application / device and the supply circuit has to have floating conditions.

(10) For AP category models: The connections to end product shall be protected against accidental disconnection in normal use or connection and disconnection can be performed only with a tool.
(11) For AP category models: The marking according to G.3.2 and G.3.3 placed on major part of footswitches for category AP.
(12) For AP category models: Electrostatic charges shall be prevented on category AP footswitch models in combination with end product (G.4.3).
(13) Footswitches with cables and connector without CA or US NRTL certification shall be supplied with a limited circuit (less than 15 Watt) in the end product (IEC 60601 Cl. 13.1.2)
(14) Foot-operated laser emission control switches shall be shrouded in end product to prevent unintentional operation (IEC 60601-2-22 Cl. 201.8.10.4.101)

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)
- Risk Management was excluded from this investigation.

Cable rating according to AWG style depends on the lead of a cable :

AWG 14-20 = max. 5A; AWG 22 = max. 2.1A; AWG 24 = max. 1.4A; AWG 26 = max. 1A; AWG 28 = max. 0.1A

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 / 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
- 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)
- Protection against ingress protection according to IEC 60529, IPX8 rating.

Supplement to Certificate of Compliance

Certificate: 2503504 **Master Contract:** 180133

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
80007964	2020-02-10	Update of cCSAus Certification 2503504/revision 70148147 of Footswitches for use with Medical Electrical Equipment to cover new model MFS MED GP712.
70148147	2017-09-18	Tests and update of Descriptive Report 2503504 due to findings in factory inspection report (trio no. CCICQ1). Concerning Model MKF 2 1S/1S-MED GP25.
70086960	2016-10-18	Update of report 2503504 to upgrade the footswitch series to the 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
70074437	2016-09-13	Update of report 2503504 to add new switching elements 1SD1S, D1S, D2S and protective flaps SK11, SK12
70014697	2015-12-22	Update Report 2503504 according to AP testing with reference to 60601-1 3rd Edition
70046560	2015-12-18	Update to report 2503504 with alternate normally open contact (microswitch) for foot switch models (2S). Format update of CofC and Descriptive Report
70001781	2013-07-11	Update for correction of errors
2503504	2013-06-17	footswitches, models WF, RF, MGF, GF2, KF(S)