Certificate of Compliance

Certificate: 70210440 **Master Contract:** 180133

Project: 80166943 **Date Issued:** 2023-08-24

Issued To: **Steute Technologies GmbH & Co. KG**
Brueckenstrasse 91
Loehne, North Rhine-Westphalia, 32584
Germany

Attention: Nina Vogelsang

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: Karl Walla
Karl Walla

C US

US

PRODUCTS

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

Medical Electrical Component, Footswitches for use with Medical Electrical Equipment / Medical Electrical System, cord connected: Non-detachable cord, Transportable, Portable, rated 25V AC / 60V DC, 5A max, Model/Type:

Series: Medical footswitches MKF/KF

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

The Footswitches nomenclature are designated as follows:

Pos I	Pos II	Pos III	Pos IV	Pos V	Pos VI	Pos VII	Pos VIII	Pos IX
Footswitch KF / MKF	Protective cover (optional mounted)	Number of Pedals	Switching function present in the pedal	Different switching function in the pedals	MED	Special product information	Base Plate	Additional customer information. e.g. customer specific description.
Example								
MKF	S	3	2S	/ 2S / 2PW	MED	USB	GP34	
MKF		2	2PW		MED		GP26	customer

POS I – Footswitch designation
KF - Pedal with stripes
MKF - Pedal with plane surface

POS II – Protective cover (optional mounted)
Blank - No protective cover
S - identifies a footswitch with a protective cover.

POS III – Number of pedals
Blank – 1 Pedal
2 – 2 Pedals
3 – 3 Pedals
4 – 4 Pedals

POS IV – Switch function per pedal(s)
(x) – Same switching elements present in each pedal(s).
Blank – Different switching elements per each pedal(s). See Pos V.

See below table for different switching function description and their electrical ratings.

POS V – Switch function per pedal(s)
Blank – Same switching element present in each pedal(s). See Pos IV.
(x) / (x) – 2 Pedal footswitch with different switching elements.
(x) / (x) / (x) – 3 Pedal footswitch with different switching elements.
(x) / (x) / (x) / (x) – 4 Pedal footswitch with different switching elements.

See below table for different switching function description and their electrical ratings.

Switching Functions, Pos IV and Pos V

(x)	Switch function description	Electrical Ratings
1S	Normally open contact (Reed)	max. 25 Vac / max. 60 Vdc. max. 1A
2S	2 Normally open contacts (reed or microswitch)	max. 25 Vac / max. 60 Vdc. max. 1A
1W	Change-over contact (Reed)	max. 25 Vac / max. 60 Vdc. max. 1A
1PW	Change-over contact (Microswitch)	max. 25 Vac / max. 60 Vdc. max. 5A
2PW	2 Change-over contact (Microswitch)	max. 25 Vac / max. 60 Vdc. max. 5A
1ÖS	normally closed and normally open contact (microswitch + Reed)	max. 25 Vac / max. 60 Vdc. max. 1A
D1S	Pressure point switch for normally open contact (Reed)	max. 25 Vac / max. 60 Vdc. max. 1A
D2S	Pressure point switch for 2 normally open contact (Reed)	max. 25 Vac / max. 60 Vdc. max. 1A
DÖS	Pressure point switch before normally closed and normally open contact (microswitch + Reed)	max. 25 Vac / max. 60 Vdc. max. 1A
1SD1S	1 normally open contact + Pressure point switch for normally open contact (Reed)	max. 25 Vac / max. 60 Vdc. max. 1A
D2S / D2S	2 x 2 pressure point switches (two per pedal), each consisting of Normally open contacts (reed)	max. 25 Vac / max. 60 Vdc. max. 1A
1Ö / 1S	Switching element consisting of 1 normally closed + 1 normally open contact	max. 25 Vac / max. 60 Vdc. max. 1A
2Ö / 2S	2 Switching elements consisting of 1 normally closed + 1 normally open contact	max. 25 Vac / max. 60 Vdc. max. 1A
1ÖS / 1ÖS	2 Switching elements (one per pedal), each consisting of 1 normally closed + 1 normally open contact	max. 25 Vac / max. 60 Vdc. max. 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 (0,5-5V)	Hall sensor with analog output signal 0,5-5 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 RS-485	Hall sensor with RS-485 output signal	Ue: 5Vdc / 200 mA

POS VI – MEDICAL USE
MED – MEDCAL USE

POS VII – Special Product information
(x*) – Special product information.
USB – USB Output
AP – Category AP
HID – Human Interface Device (see description below).

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.

POS VIII– Base plate type
Blank – No Base plate (Footswitch with only KF/MKF pedals).
(x**) – Base plate type.

(x**) 1- pedal	(x**) 2- pedal	(x**) 3- pedal	(x**) 4- pedal
GP 11	GP 25	GP 32	GP 47
GP 12	GP 26	GP 33	GP 411[2)]
GP 17	GP 212	GP 34	
SK 12[1)]	GP 211[2)]	GP 311[2)]	
GP 111[2)]			

POS IX – Information for customer (e.g. customer identification).

Note
- Information in brackets are used only if the particular description applies to the footswitch.
- [1)] SK 12 footswitch has protective PA6 flap.
- [2)] Footswitches with baseplate series GPX11 are rated only for IPX8; All other baseplates footswitch are rated for IPX8 and IPX5 (No differences to IPX8 version).

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: IPX8 for GPX11 / IPX8 and IPX5 for all other baseplates.
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.
9. Software revision: No PEMS

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Conditions of Acceptability:

1. Evaluated to CAN/CSA-C22.2 NO. 60601-1:08 + AMD1:2014 + Amendment 2:2022 to CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009(R2012) AND A2:2010(R)2012 (CONSOLIDATED TEXT) + ANSI/AAMI ES60601-1:2005/A2:2021 excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17). 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. Equipment needs to be re-evaluated in combination with end product. Technical Consideration shall be evaluated in end device.
4. The end use manufacturer has to incorporate the necessary information within their user manual. Steute provide information for the end product manufacturer.
5. The end product manufacturer has to incorporate the footswitch in their risk and usability evaluation. Steute shall support them with the footswitch related hazards.
6. The subject models are evaluated only as components for use only in or with complete Medical equipment, where the suitability of the combination is to be determined by the Accepting NCB when installed in the end-product.
7. The ME COMPONENT is intended to receive its power from other electrical equipment in an ME SYSTEM. Interconnection of this medical device with other medical devices, medical used systems or non-medical devices shall be evaluated to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 (Clause 16) in the final system configuration by the end product manufacturer.
8. The circuit isolation of two means of protection (2 MOP) to the mains circuit have to be provided in the end application / device and the supply circuit has to have floating conditions (1 MOP to PE).
9. Footswitches with power above 100VA shall be equipped with cables of flammability classification VW-1 / FT-1, if power is between 15 VA and 100 VA the cable insulation shall be of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide, no cable flammability classification requirements for power circuit less than 15 Watt according IEC 60601-1 Cl. 13.1.2.

10. 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.
11. 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.
12. 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.
13. 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.
14. For AP category models: The marking according to G.3.2 and G.3.3 placed on major part of footswitches for category AP. The Technical description shall contain the explanation of the symbol AP present for applicable footswitches those meeting Category AP (Annex G) requirements.
15. For AP category models: Electrostatic charges shall be prevented on category AP footswitch models in combination with end product (G.4.3).
16. 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: Scope of footswitch evaluation defers the following clauses to be determined as part of the end product investigation:

- Clause 4.2 (Risk Management),
- Clause 4.3 (Essential performance),
- Clause 6.2 (Classification of ME equipment and ME systems)
- Clause 12.2 (Usability),
- Clause 7.4 (Marking of controls and instruments),
- Clause 7.5 (Safety Signs),
- Clause 7.9 (Accompanying Documents),
- Clause 8.4 (Limitation of voltage, current or energy),
- Clause 8.5 (Separation of parts),
- Clause 8.7 (Leakage current),
- Clause 8.8 (Insulation),
- Clause 8.10.4 (Cord-connected hand-held parts and cord-connected foot-operated control devices)
- Clause 8.11.3 Power supply cords,
- Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- Clause 10 (Radiation),
- Clause 11.1 (Temperatures)
- Clause 11.3 (Constructional requirements)
- 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 12 (Accuracy),
- Clause 13 (Hazardous and single fault conditions),
- Clause 14 (PEMS),
- Clause 16 (ME Systems)

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

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APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:14 (R2018)	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition + Amendment 1:2012)
Amendment 2:2022 to 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, third edition/Amendment 2:2020)

Reference Standards

CAN/CSA-C22.2 NO. 60601-2-2:2019	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 60601-2-2:2017, sixth edition,2017-03). Only Clause 201.8.10.4.101.4 and 201.11.6.5 a) 103 were considered during the evaluation.
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) Only Clause 201.11.6.5.101 & 201.11.6.5.103 was considered during the evaluation.
Amendment 1:2019 to CSA-C22.2 No. 60601-2-43:11 (R2019)	Amendment 1:2019 to 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/Amendment 1:2017) Only Clause 201.11.6.5.101 & 201.11.6.5.103 was considered during the evaluation.
Amendment 2:2021 to CSA-C22.2 No. 60601-2-43:11	Amendment 2:2021 to 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/Amendment 2:2019)

	Only Clause 201.11.6.5.101 & 201.11.6.5.103 was considered during the evaluation.
CSA-C22.2 No. 60601-2-22:23	Medical Electrical Equipment part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment (Adopted IEC 60601-2-22:2019, fourth edition) Only Clause 201.8.10.4.101was considered during the evaluation.

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005/(R)2012, AND A1:2012, C1:2009(R2012) AND A2:2010(R)2012 (CONSOLIDATED TEXT)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD).
ANSI/AAMI ES60601-1:2005/A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment 2 (IEC 60601-1:2005/A2:2020).

Reference Standards

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 Only Clause 201.8.10.4.101.4 and 201.11.6.5 a) were considered during the evaluation.
IEC 60601-2-43:2010/A2:2019	Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures Only Clause 201.11.6.5.101 & 201.11.6.5.103 was considered during the evaluation.
IEC 60601-2-22:2019	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment Only Clause 201.8.10.4.101 was considered during the evaluation.

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Notes:

Products certified under Class C878001, C878081 have been certified under CSA's ISO/IEC 17065 accreditation with the Standards Council of Canada (SCC). www.scc.ca

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
80166943	2023-08-24	Update of cCSAus certification 70210440 / 80099991 for Medical Electrical Component / cord-connected foot switches to new CAN/CSA / ANSI/AAMI 60601-1 Amendment 2 standard and further minor changes (alternate material for GP 25, update of standard for DC switches, formal corrections).
80099991	2022-01-31	Update of cCSAus Certification 70210440 of cord-connected footswitches MKF-Series according to IEC 60601-1 Edition 3.1., to cover: -Transfer of wired foot switches with base plate GP11, GP12, GP17, GP25, GP26, GP212, GP32, GP33, GP34, GP47, SK12, (M)KF (footswitches without baseplate) from Certification 2503504 (project 80007964). - Addition of risk management for the (M)KF footswitches with baseplate GP11, GP12, GP17, GP25, GP26, GP212, GP32, GP33, GP34, GP47, SK12, (M)KF (footswitches without baseplate). - Addition of new alternative material for base plates GP17, GP212 and GP47 (adding new alternative material PC/PET-Emerge), - Addition of new dimensions for base plate GP32/33 (Updated tooling/changed overall dimensions), - Evaluation according to Annex G, Category AP (Protection against HAZARDS of ignition in a flammable anaesthetic Mixtures with AIR), requirements for GPx11 footswitches, - Update of LOCC to consider the new modification and changes.
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.