Certificate of Compliance

Certificate: 70000287 **Master Contract:** 180133

Project: 80187241 **Date Issued:** 2024-03-06

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', 'US' and▲

Issued by: *Merve Betül Kücükkahraman*
Merve Betül Kücükkahraman

PRODUCTS

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

Series:	**(x): Switching function**	**Description:**	**(x*): Baseplate**	**(x**): Information e.g. customer**
(M)KF (x) – SW2.4LE-MED (x*) (x**)	2S	2 normally open contacts (reed)	GP212[1)]	
	2PW	2 Change-over contact (microswitch)	GP34[1)]	
(M)KF 2 (x) /***(x)*** – SW2.4LE-MED (x*) (x**)	1S D1S	1 normally open contact + pressure point	GP211[2)]	
(M)KF 3 (x) – SW2.4LE-MED (x*) (x**)	D2S	Pressure point +2 normally open contact	GP111[2)]	
(M)KF 4 (x) – SW2.4LE-MED (x*) (x**)			GP311[2)]	
			GP411[2)]	

SK13[2)]

Receiver:
REC SW2.4-LE-MED AG43
REC SW2.4LE-MED AG43 5VDC
REC SW2.4LE-MED 5VDC[3)]

Receiver also available without enclosure. See conditions of acceptability in this case.
Note:

- 1) Footswitches operated with re-chargeable batteries.
- 2) Footswitches operated with non-chargeable (primary) batteries.

Input: 100 – 240 V ~, 50 – 60 Hz, 160 – 80 mA;
Output: 9 V ⎓, 800 mA
(charger FOX6 Type FW8002M/09)
Input: 100 – 240 V ~, 50 – 60 Hz, 160 – 80 mA;
Output: 9 V ⎓, 800 mA
(charger FOX6 Type FW8002.1M/09)

3.6 V DC, 2.2 Ah, 7.92 Wh (rechargeable battery-operated footswitches)
3.6 V DC, 2.90 Ah, 9.8 Wh (rechargeable battery-operated footswitches)
4.5 V DC (non- rechargeable battery-operated footswitches)
7.5 – 24 V DC, 2.4 W (receiver AG43)
5 V DC, 2.4 W (receiver AG43 5VDC)
5 V DC, 500 mW (receiver REC SW2.4LE-MED 5VDC)

1. Medical device protection against electric shock: Internally powered
2. Applied Part protection against electric shock: No applied part/Not Classified
3. Degree of protection against ingress of water or particulate matter: IPX8 for footswitches / IP40 for receiver
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: for LE footswitches: 0 to +45 °C, 10 to 100 % RH, 700-1060 hPa
   charging mode: 0 to +40 °C, 10 to 100 % RH, 800-1060 hPa
   for LE receiver: -10 to +60 °C, 10 to 75 % RH, 700-1060 hPa
9. Software / Revision: footswitch LE: V02.20 (software safety Class C)
   receiver LE: V02.20 (software safety Class C)

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Conditions of Acceptability:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 (R2018) + 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), 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 and receiver in the end product.

(11) The receiver shall be built in an enclosure with fire protection (FV-1 or better) or supplied with a limited circuit (less than 15 Watt) in the end product.

(12) For receivers without enclosure: The receiver is intended for building in. Final installation should comply with the enclosure, mounting, marking, spacing, and separation requirements. In addition, Temperature, Leakage Current, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end device evaluation.

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 12.2 (Usability),
- Clause 7.5 (Safety Signs),
- Clause 7.9 (Accompanying Documents),
- Clause 8.2. Requirements related to power sources (for receiver),
- 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 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- Clause 10 (Radiation),
- Clause 11.3 (Constructional requirements)
- Clause 12 (Accuracy),
- Clause 13 (Hazardous and single fault conditions),
- Clause 14 (PEMS),
- Clause 16 (ME Systems)

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:14(R2018)	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)
Amendment 2: 2022 to CSA-C22.2 No.60601-1:14	Amendment 2: 2022 to 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, third edition / Amendment 2: 2020)
CAN/CSA-C22.2 No.60601-1-6:11(R2016)	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition)
Amendment 1:2015 to CAN / CSA-C22.2 No. 60601-1-6:11 (R2016)	Amendment 1:2015 to CAN / CSA-C22.2 No. 60601-1-6:11 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition / Amendment 1:2013)
Amendment 2: 2021 to CAN/CSA-C22.2 No.60601-1-6:11	Amendment 2: 2021 to CAN/CSA-C22.2 No.60601-1-6:11 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition, Amendment 2:2020))

Reference standards

CSA-C22.2N0.60601-2-2:19	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) Clause 201.8.10.4.101.4 and 201.11.6.5 a) are applicable only
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) 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) Clause 201.11.6.5.101 and 201.11.6.5.103 are applicable only
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) Clause 201.11.6.5.101 and 201.11.6.5.103 are applicable only
Amendment 2: 2021 to CAN/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) 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 ES60601-1:2005 / A2:2021	Amendment 2:2021 to ANSI/AAMI ES60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment 2 (IEC 60601-1:2005 / A2:2020).
IEC 60601-1-6:2010	Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-6:2010 / A1:2013	Amendment 1:2013 to IEC 60601-1-6:2013 Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-6:2010 / A2:2020	Amendment 2:2020 to IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

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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 Clause 201.8.10.4.101.4 and 201.11.6.5 a) are applicable only
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 Clause 201.8.10.4.101 is applicable only
IEC 60601-2-43:2022	Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures Clause 201.11.6.5.101 and 201.11.6.5.103 are applicable only

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
80187241	2024-03-06	Update of cCSAus certification 70000287 for Medical Electrical Component / wireless foot switches with receiver MKF / KF Series to new CAN/CSA / ANSI/AAMI 60601-1 Amendment 2 standard and further minor changes (alternate material, update of standard for DC switches, formal corrections)
80063323	2021-07-23	Update cCSAus Certification 70000287/revision 80038653 for Medical Electrical Component, Wireless footswitches with receiver for use with certified medical electrical equipment to cover new Power Supply (charger) FOX6 FW8002.1M/09 according to 60601-1 Edition 3.1, and perform changes to critical component list, update to RM file to adapt new format, and delisting of footswitch model(s) GP17 and SK19 from certification reports and certification records.
80038653	2020-03-27	Update of cCSAus Certification 70000287/revision 70203401 to correct CofC product certification history.
70203401	2019-02-27	Update cCSAus Certification 70000287 to cover new footswitch models SK13, GP111,GP311, GP411, receiver REC SW2.4LE-MED 5VDC and update of new basis software for all footswitches and receiver.
70200101	2018-10-16	Update cCSAus Certification 70000287 for Medical Electrical Component, Wireless footswitches with receiver to cover new O-rings and correction of List of Crictical Components to add alternative cable.
70162261	2018-05-25	Update cCSAus Certification for Medical Electrical Component, Wireless footswitches Series with receiver, according to IEC 60601-1 E dition 3.1. based on report 70000287 to cover new enclosure after successfully completion of Line QL-0015551.
70175326	2018-04-27	Replacement change-order 70162260CO01 (Optimus): Update of cCSAus Certification for Medical Electrical Component, Wireless footswitches Series with receiver, to cover new power supp ly FOX6 and SK12(SK19) according to IEC 60601-1 Edition 3.1. based on report 70000287.

70162260	2018-03-23	Update cCSAus Certification for Medical Electrical Component, Wireless footswitches Series with receiver, to cover new wireless footswitch GP211 and receiver model AG43 5V according to IEC 60601-1 Edition 3.1. based on report 70000287
70120365	2017-06-27	Update of Report 70000287 to cover new models
70000287	2016-04-27	Original Certification