Certificate of Compliance

Certificate: 70000287 **Master Contract:** 180133

Project: 80063323 **Date Issued:** 2021-07-23

Issued To: **steute Technologies GmbH & Co. KG**
Brueckenstrasse 91
Loehne, North Rhine-Westphalia, 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: *Santhosh Reddy Veliminate*
Santhosh Reddy Veliminate

C US US

PRODUCTS

CLASS - C878001 - MEDICAL ELECTRICAL EQUIPMENT (Canadian adopted IEC 60601-1 3rd edition)
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT (US Adopted IEC 60601-1 3rd edition)

Medical Electrical Component, Wireless footswitches with receiver, Model/Type:

Series:	(x): Switching function	Description:	(x*): Baseplate	(x**): Information e.g. customer
(M)KF (x) – (RF) SW2.4-MED (x*) (x**)	1S 2S	Normally open contact (reed) 2 normally open contacts (reed or microswitch)	GP212[1)]	

(M)KF 2 (x) / (x) – (RF) SW2.4-MED (x*) (x**)	1W	Change-over contact (reed)	GP34[1)]
	1PW	Change-over contact (microswitch)	GP211[2)]
(M)KF (x) – SW2.4LE-MED (x*) (x**)	2PW	2 Change-over contact (microswitch)	
	1S D1S	1 normally open contact + pressure point	GP111[2)]
(M)KF 2 (x) / (x) – SW2.4LE-MED (x*) (x**)	2SD1Ö	2 normally open contact (reed) + pressure point + 1 normally close contact (microswitch)	GP311[2)]
(M)KF 3 (x) – SW2.4LE-MED (x*) (x**)	D1S	Pressure point +1 normally open contact	GP411[2)]
(M)KF 4 (x) – SW2.4LE-MED (x*) (x**)	D2S	Pressure point +2 normally open contact	SK13[2)]
	HS	Hall sensor with analog output signal 0-3,3V 0-5 V 0,5-5 V 0-7,5 V 0-10 V (with AG 43 U_e=7.5 V DC -12 V DC)	

Receiver:
REC RF SW2.4-MED AG 43
REC SW2.4-LE-MED AG43
REC SW2.4LE-MED AG43 5VDC
REC SW2.4LE-MED 5VDC[3)]

Note:

- 1) Footswitches operated with re-chargeable batteries.
- 2) Footswitches operated with non-chargeable (primary) batteries.
- 3) Receiver also available without enclosure. See conditions of acceptability in this case.
- Only baseplate type GP212 is built with SW2.4RF and SW2.4LE communication system; while the rest of baseplates are only built with SW2.4LE communication system.

Rated: Input: 100 – 240 V ~, 50 – 60 Hz, 150 mA;
Output: 7.5 ⎓, 800 mA
(charger GPP6 (FW7662M/08) REF 1230374)
Input: 100 – 240 V ~, 50 – 60 Hz, 250 – 110 mA;
Output: 9 V ⎓, 600 mA
(charger GPP6 (FW7662M/09) REF 1457950)
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 RF footswitches: 0 to +45 °C, 10 to 100 % RH, 800-1060 hPa
   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 RF receiver: -10 to +60 °C, 30 to 75 % RH, 800-1060 hPa
   for LE receiver: -10 to +60 °C, 10 to 75 % RH, 700-1060 hPa
9. Software / Revision: footswitch RF: V2.7.0 (software safety Class A) /
   footswitch LE: V02.20 (software safety Class C)
   receiver RF: V2.8.0 (software safety Class A) /
   receiver LE: V02.20 (software safety Class C)

Conditions of Acceptability:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005 /C1:2009 (R2012) and A2 (R2012), 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	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. 60601-1-6:11 + AMD1: 2015	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, 2010-01 + A1:2013 – edition 3.1 This consolidated version consists of the third edition (2010) and its amendment 1 (2013-10)).
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) were considered during the evaluation.
CAN/CSA-C22.2 NO. 60601-2-22A:08 + AMD1 (R2014)	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)). Only Clause 201.8.10.4.101 were considered during the evaluation.

CAN/CSA-C22.2 NO. 60601-2-43:11+AMD1: 2019	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 + amendment 1, 2017-08) Only clause 201.11.6.5.101 and 201.11.6.5.103 were considered during the evaluation.

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)
IEC 60601-1-6:2006 + A1:2013	Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

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 60601-2-22:2007+A1: 2012	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 were considered during the evaluation.
IEC 60601-2-43:2010+A1:2017	Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures Only Clause 201.11.6.5.101 and 201.11.6.5.103 were considered during the evaluation.

Supplement to Certificate of Compliance

Certificate: 70000287 **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
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.
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
70120365	2016-04-27	Update of Report 70000287 to cover new models