Ref. Certif. No.

CA/22839/CSA

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product	Wireless footswitches with receiver
Name and address of the applicant	steute Technologies GmbH & Co. KG Brückenstraße 91 32584 Löhne Germany
Name and address of the manufacturer	steute Technologies GmbH & Co. KG Brückenstraße 91 32584 Löhne Germany
Name and address of the factory Note: *When more than one factory, please report on page 2*	steute Technologies GmbH & Co. KG Brückenstraße 91 32584 Löhne Germany ☐ Additional Information on page 2
Ratings and principal characteristics	Refer to Page 2 of Certificate
Trademark (if any)	.steute
Customer's Testing Facility (CTF) Stage used	N/A
Model / Type Ref.	Refer to Page 2 of Certificate
Additional information (if necessary may also be reported on page 2)	☐ Additional Information on page 2
A sample of the product was tested and found to be in conformity with	IEC 60601-1:2005/AMD1:2012 including ND for CA and US, excluding requirements Electromagnetic compatibility (Clause 17) and Biocompatibility (Clause 11.7)
As shown in the Test Report Ref. No. which forms part of this Certificate	CB 180133-70217682 (70217682)

This CB Test Certificate is issued by the National Certification Body

CSA GROUP™

CSA Group
178 Rexdale Boulevard
Toronto, ON M9W 1R3 Canada

Date: 2019-05-07

Signature: Michel Brossoit, P.Eng.

Model/Type reference:

Series:	**(x): Switching function**	**Description:**	**(x*): Baseplate**	**(x**): Information e.g. customer**
(M)KF (x) – (RF) SW2.4-MED (x*) (x**) (M)KF 2 (x) – (RF) SW2.4-MED (x*) (x**) (M)KF (x) – SW2.4LE-MED (x*) (x**) (M)KF 2 (x) – SW2.4LE-MED (x*) (x**) (M)KF 3 (x) – SW2.4LE-MED (x*) (x**) (M)KF 4 (x) – SW2.4LE-MED (x*) (x**)	1S 2S 1W 1PW 2PW 1S D1S 2SD1Ö D1S D2S HS	Normally open contact (reed) 2 normally open contacts (reed or microswitch) Change-over contact (reed) Change-over contact (microswitch) 2 Change-over contact (microswitch) 1 normally open contact + pressure point 2 normally open contact (reed) + pressure point + 1 normally close contact (microswitch) Pressure point +1 normally open contact Pressure point +2 normally open contact 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)	GP212 GP17 GP34 GP211 SK19 GP111 GP311 GP411 SK13	

REC RF SW2.4-MED AG 43
REC SW2.4-LE-MED AG43
REC SW2.4LE-MED AG43 5VDC
REC SW2.4LE-MED 5VDC

Note:
- GP17 not for LE models available
- Receivers are also available without enclosure. See conditions of acceptability in this case.

Ratings:
Input: 100 – 240 V ~, 50 – 60 Hz, 150 mA;
Output: 7.5 ⎓, 800 mA
(power supply GPP6 REF 1230374)
Input: 100 – 240 V ~, 50 – 60 Hz, 250 – 110 mA;
Output: 9 V ⎓, 600 mA
(power supply GPP6 REF 1457950)
Input: 100 – 240 V ~, 50 – 60 Hz, 160 – 80 mA;
Output: 9 V ⎓, 800 mA
(power supply FOX6 REF 5770586 Type FW8002M/09)
3,6 V DC, 2,2 Ah, 7,92 Wh (battery-operated footswitches)
3,6 V DC, 2,90 Ah, 9,8 Wh (battery-operated footswitches)
4,5 V DC (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)

Conditions of acceptability:

(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 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:

1. 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 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- Clause 10 (Radiation),
- Clause 14 (PEMS),
- Clause 16 (ME Systems)

Additional information (if necessary)
Information complémentaire (si nécessaire)

Date: 2019-05-07

Signature: Michel Brossoit, P.Eng.