Ref. Certif. No.

CA/19489/CSA

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

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product Produit	Foot switch for use with medical electrical equipment: Series (page 2, 3 and 4)
Name and address of the applicant Nom et adresse du demandeur	steute Schaltgeraete GmbH & Co. KG Brueckenstrasse 91, 32584 Loehne Germany
Name and address of the manufacturer Nom et adresse du fabricant	Same as applicant.
Name and address of the factory Nom et adresse de l'usine Note: *When more than one factory, please report on page 2* Note: *Lorsque il y plus d'une usine, veuillez utiliser la 2ème page*	steute Schaltgeraete GmbH & Co. KG Brueckenstrasse 91, 32584 Loehne Germany ☐ Additional Information on page 2
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	25 Vac / 60 Vdc, 1A, 25Vac / 60 Vdc, 5A
Trademark (if any) Marque de fabrique (si elle existe)	steute Medizintechnik
Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur	
Model / Type Ref. Ref. De type	Refer to pages 2, 3 and 4 of Certificate.
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2ème page	☒ Additional Information on page 2
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 + CORR. 1:2006 + CORR. 2:2007 + A1:2012, excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Usability (Clause 7.1.1 and 12.2), Biocompatibility (Clause 11.7) and Risk management (ISO14971, Clause 4.2). These exclusions shall be evaluted in the end product/device.
As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	CB 180133-2503504 (70086960)

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**

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

Date: 2016-10-18

Signature: Michel Brossoit, P.Eng.

Model / Type Ref.

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)	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
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

(x)	Switch function description	Electrical Ratings
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
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

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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)

(x)**	**Baseplate**	
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)	

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

Note: During the time of testing applicable clauses were considered for IEC 60601-2-22 , IEC 60601-2-43

Conditions of acceptability:

(1) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
(2) 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.
(3) Equipment needs to be re-evaluated in the end product.
(4) Steute provides information for the end product manufacturer. The end use manufacturer has to incorporate the necessary information within their user manual.
(5) The end product manufacturer has to incorporate the footswitch in their risk evaluation. Steute can support them with the footswitch related hazards.
(6) 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.
(7) 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.
(8) 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.
(9) 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.
(10) For AP category models: The marking according to G.3.2 and G.3.3 placed on major part of footswitches for category AP.
(11) For AP category models: Electrostatic charges shall be prevented on category AP footswitch models in combination with end product (G.4.3).

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

Date: 2016-10-18

Signature: Michel Brossoit, P.Eng.