



Certificate of Compliance

Certificate: 70129804

Master Contract: 269920

Project: 70129804

Date Issued: 2018-12-10

Issued to: ASA Schalttechnik GmbH
F.-A.-Meyer-Straße 4
Porta Westfalica, Nordrhein-Westfalen 32457
GERMANY
Attention: Mike Funke

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: Ronald García
Ronald Garcia

PRODUCTS

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

CLASS - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS

Medical Electrical Component, footswitches for Medical Electrical Equipment or System, Model/Type:

FM followed by 1, 2, 3, 4, 5 or 6, may be followed by, Blank

- Without console, K11 for FM1, K21 for FM2, K31 for FM3, Ergo for FM3

may be followed by (Switch insert per pedal), Blank – Without first switch,

(x*)(x**)1 - first switch, (x*)(x**)2 - first and second switch (if same type), USB - Human Interface Device (Keyboard emulator), may be followed by Blank – momentary function, D – with pressure point,

R – with latching function, may be followed by, Blank – without second switch, (x*)(x**)1 - second switch,

may be followed by F - Permanently connected supply cable,

may be followed by, 1, 2, 3 or 4, may be followed by Blank (without guard), or may be followed by U (with guard)

cord-connected: Non-detachable cord, portable rated: 25 VAC / 60 VDC, max. 5A (depends on footswitch)

1. Medical device protection against electric shock: Class II
2. Applied Part protection against electric shock: No applied part/Not Classified
3. Degree of protection against ingress of water or particulate matter: IPX1 to IPX8
4. Method of Sterilization: None

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME
CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product

Footswitches for ME Equipment / ME System

Name and address of the applicant

 ASA Schalttechnik GmbH
 F.-A.-Meyer-Straße 4, 32457 Porta Westfalica, Germany

Name and address of the manufacturer

 ASA Schalttechnik GmbH
 F.-A.-Meyer-Straße 4, 32457 Porta Westfalica, Germany

Name and address of the factory

 ASA Schalttechnik GmbH
 F.-A.-Meyer-Straße 4, 32457 Porta Westfalica, Germany

Note: When more than one factory, please report on page 2

 Additional Information on page 2

Ratings and principal characteristics

 25 V AC, max. 5 A / 48 V DC, max. 1 A or 25 V AC, 0.1 A /
 30 V DC, 0.1 A (Depends on switch)

Trademark (if any)

Customer's Testing Facility (CTF) Stage used

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 national deviations of CA and US excluding Electromagnetic compatibility (Clause 17) and Biocompatibility (Clause 11.7)

As shown in the Test Report Ref. No. which forms part of this Certificate

CB 269920-70129804 (70129804)

This CB Test Certificate is issued by the National Certification Body


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



Date: 2018-12-07

Signature: Michel Brossoit, P.Eng.