



Ref. Certif. No.

SE-81464

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST
CERTIFICATES FOR ELECTRICAL EQUIPMENT
(IECEE) CB SCHEMESYSTEME CEI D'ACCEPTATION MUTUELLE DE
CERTIFICATS D'ESSAIS DES EQUIPEMENTS
ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product
Produit

Power supply unit

Name and address of the applicant
Nom et adresse du demandeurPowerbox AB
Västra Storgatan 22
SE-646 35 Gnesta, SwedenName and address of the manufacturer
Nom et adresse du fabricant

Same as applicant

Name and address of the factory
Nom et adresse de l'usineNote: When more than one factory, please report on page 2
Note: Lorsque il y plus d'une usine, veuillez utiliser la 2^{ème}AMC Electronics Manufactory
Yangtian Road, Longhe Industrial Zone
Longgang town, Longgang District, Shenzhen, Guangdong
Province 518116 Shenzhen, P.R. CHINARatings and principal characteristics
Valeurs nominales et caractéristiques principalesInput: 100-240VAC, 47-63Hz, 0.6A
Output: 12VDC, 2.5A or 15VDC, 2.0A or 24VDC, 1.25A
Built-in PSU for Class II applicationsTrademark (if any)
Marque de fabrique (si elle existe)

P	R	POWERBOX
B	X	Mastering Power

Type of Manufacturer's Testing Laboratories used
Type de programme du laboratoire d'essais
constructeur

-

Model / Type Ref.
Ref. De type

OFM30

Additional information (if necessary may also be
reported on page 2)
Les informations complémentaires (si nécessaire,
peuvent être indiqués sur la 2^{ème} page)

See 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 and A1

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

1515856STO-001

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de CertificationIntertek Semko AB
Box 1103
SE-164 22 Kista, Sweden
Int +46 8 750 00 00

Signature:

Bo Berglöf

Date: 9 December 2015

Additional information:

OFM30 is a power supply unit (PSU) intended to be built-into MEE that can be used in both hospital and home care environments.

Even though the MEE does not include any applied parts, by request of manufacturer the MEE has been evaluated for patient leakage current.

All isolations, including the isolation between the primary and the secondary circuit, has been evaluated for MOPP requirements.

Models:

OFM30 5025 output: 12VDC, 2.5A

OFM30 5026 output: 15VDC, 2.0A

OFM30 5028 output: 24VDC, 1.25A

Home care environment

MEE is intended for home care appliances, but a full report for IEC 60601-1-11 was judged not applicable. However, IEC 60601-1-11 was considered during the evaluation:

- For applicable requirements, voltage was 85% instead of 90% (IEC 60601-1-11 subclause 4.1)
- Environmental conditions (IEC 60601-1-11 subclause 4.2) was addressed by review of a rational by the manufacturer.

The product is also in conformity with the following standards:

- ANSI/AAMI ES60601-1: 2005 / A2:2010 as shown in Test Report No. 1515856STO-001
- CAN/CSA-C22.2 No. 60601-1:08 as shown in Test Report No. 1515856STO-001

Conditions of Acceptability:

- Intended to be built into an end-use product, thus several clauses and sub clauses are not applicable and shall be checked in the end-use application (see Test Report for details)
- EMC shall be evaluated in the end-use application
- It is anticipated that the end-product manufacturer will have access to the above stated condition

The following have not been evaluated by Intertek Semko AB:

- RMF and IEC 60601-1-6 has been excluded since MEE is a PSU and as such is not considered an end-use product. RMF and Usability shall be evaluated in the end-use application.

Date: 9 December 2015

Signature: 