

Firma / Company**FRIWO Gerätebau GmbH**

Gerätetyp / Type: OF65M/12
Artikelnr. / Part-No.: 1897107
Zeichnungsnr. / Drawing-No.: 15.4312.500-00
Datum / Date: 04.03.2014

Sachbearbeiter Verkauf / Contact Sales: Frederick Balzer
Sachbearbeiter Mechanik / Contact Mech. Eng.: Angela Chen
Sachbearbeiter Elektronik / Contact Elec. Eng.: KSTWN
Freigabe App. / Approved App. PRFFR
Freigabe / Approved KSTAL

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We may ask you to return one signed copy of the specification for our records as having your approval. Unless you do not enter your objection to the latest specification issue without delay, your acceptance and release for production on the basis of this specification is deemed to be given.

Kundenfreigabe / Customer Release:

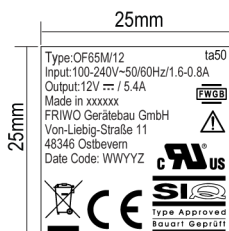
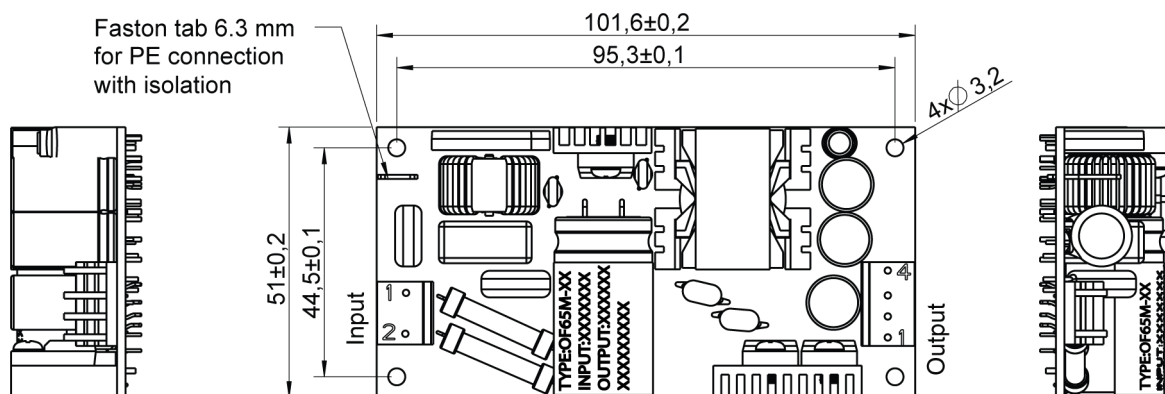
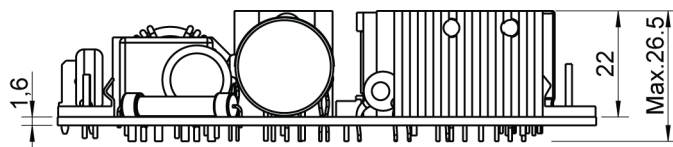
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Unterschrift / Signature:

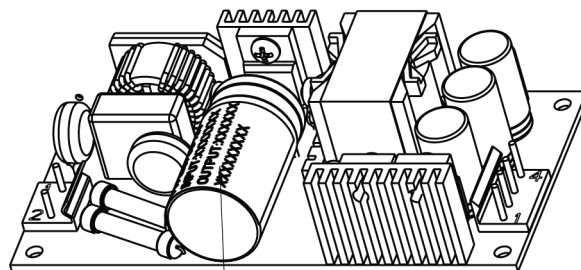
Index / Rev.	Datum / Date	Name	Einzelheit / Detail
④	2017/1/19	Werk	Printing of label changed, see point 1, updated declaration of ...
⑤	2019/1/15	Brokhage	Operating altitude, atmospheric pressure and reference test set ...
⑥	2019/2/25	Brokhage	The label on the capacitor has been revised, see point 1. Point ...
⑨	2019/12/2	Brokhage	Layer/divider changed and Info for ESD bag added, see point 2.1. ...
⑧	2020/8/6	Frenkie	PCR P003577128; MR2020-4-10292. Deleted point 5.1, updated "Safety-standard acc. to", "Protection class" and "Low Voltage Directive". See points 4, 5a).

1 Gehäuse / Housing:

Gehäusetyp / housing type: OPEN FRAME



Printing: Black letter on white base
 Material: copperplate paper with bright/shining surface (UL/CSA approval)
 Coating: Acrylic adhesive backing
 To be manufactured by UL/CSA qualified vendor
 Storage temperature -25 degC ~ +85 degC
 The thickness of label is 0.12 +/- 0.02mm
 Datumscode/date-code "WWYYZ"
 W=Woche/week Y=Jahr/year Z=Fertigungsstätte/Factory code
 (Note: without mark = FRIWO Gerätebau GmbH)
 Made in XXXXXX = manufacturing country (Germany / Poland / Vietnam)



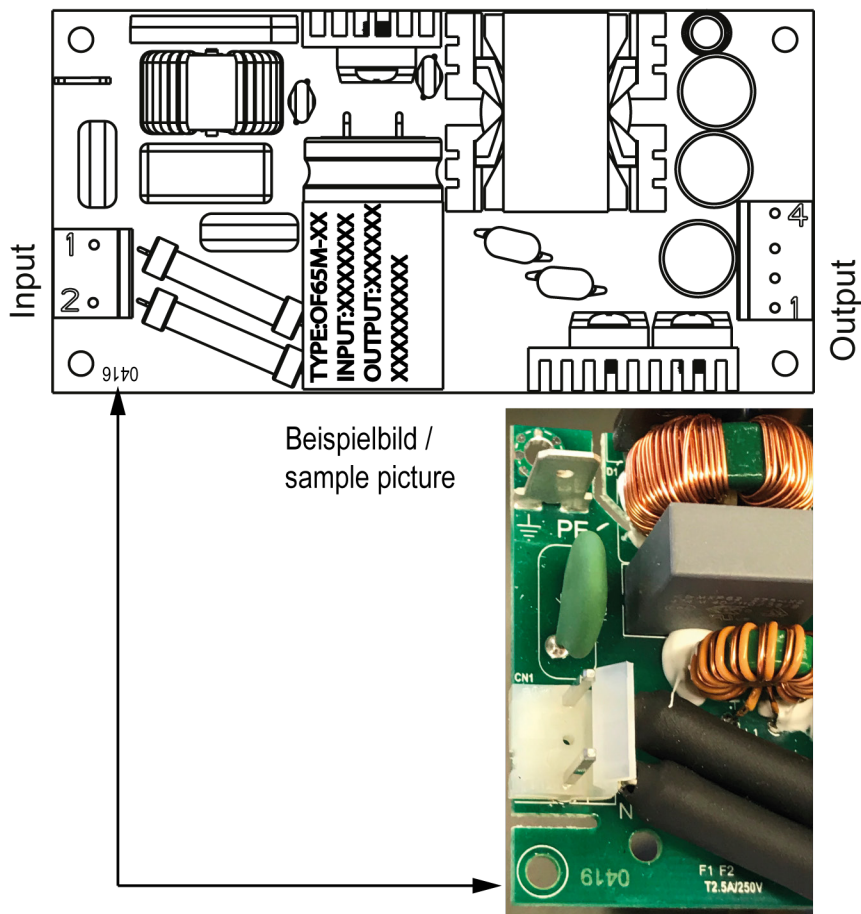
pasted label (25mmx25mm)

Input pin	1	2	Output 1 pin	1	2	3	4
	L	N		-	-	+	+

Item	Molex connector type or equivalent	Mating connector molex type or equivalent
Input	0010634027	09501021
Output 1	0009652048	09501041

1.1

Position des Datecodes nach der elektrischen Prüfung /
position of the date code after the electrical test



Der Datecode auf der PCB und auf dem Label müssen übereinstimmen /
the date code on the PCB and on the label must match.

2 Verpackung / Packaging

2.1 Einzelverpackung / Individual packaging:

Zwischenlage / Layer: 13.0002.056-03

Fächersteg / Divider: 15.2057.556-10

PCB/A in ESD-Beutel 1822389 einlegen,
ESD-Etikett 1835676 auf den ESD-Beutel kleben./
Put PCB/A into ESD bag 1822389,
paste ESD label 1835676 on the ESD bag.

2.2 Sammelverpackung / bulk packaging: 56 er UMKARTON / Carton 56

2.2.1 Aussenabmessungen / Outer dimensions: 433mm x 338mm x 344mm

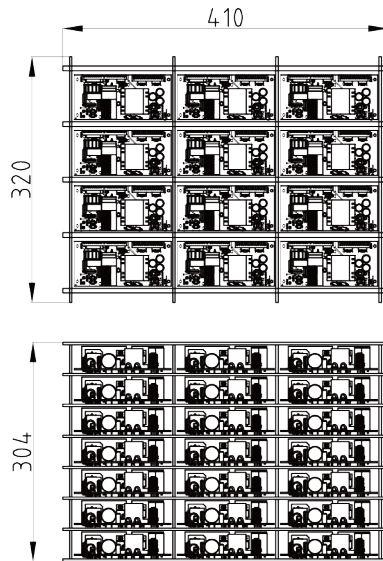
2.3 Anzahl der Geräte pro Umkarton /
amount of units per master carton: 84

2.4 Gewicht pro Stück / weight per unit: 137 g

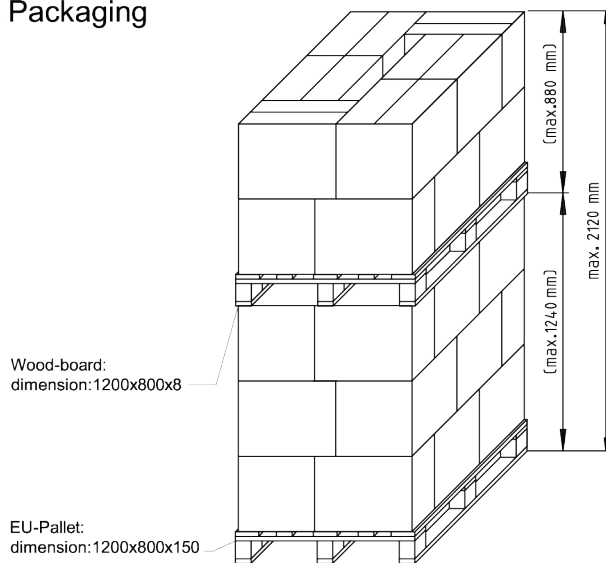
2.5 Lagertemperatur / storage temperature: -25°C - +85°C / 10 to 95 rel. hum.

2.6 Verpackungsanweisungen / packaging specification:

Inner Packaging



Pallet Packaging



Notes:

- 1) 84 pcs per carton
- 2) 6 carton per layer
- 3) 2 layer per pallet
- 4) total 1008 pcs per 2-layer-pallet

Notes:

- 1) 84 pcs per carton
- 2) 6 carton per layer
- 3) 3 layer per pallet
- 4) total 1512 pcs per 3-layer-pallet

1 stack (2-layer-pallet and 3-layer-pallet)
= (1008 pcs. + 1512 pcs.)
= 2520 pcs per stack

22 pallets (11 stacks of each type)
=27720 pcs. per 20ft container

48 pallets (24 stacks of each type)
=60480 pcs. per 40ft container

3 Elektrische Prüfbedingungen / electrical tests

3.1 Alle nachstehend aufgeführten Werte werden bei +20°C Raumtemperatur und nach 15 Minuten Einschaltdauer gemessen.

All values listed below are measured at an ambient temperature of +20°C and after 15 minutes of operation.

3.2 Eingangsdaten / Input data:

3.2.1 Nenneingangsspannung /	100-240V AC $\pm 10\%$
Nominal input voltage :	100-240V AC $\pm 10\%$

3.2.2 Nenneingangsfrequenz /	47-63Hz
Nominal input frequency:	47-63Hz

3.2.3 Nenneingangsstrom /	1.6Arms @ bei Maxlast
Nominal input current:	1.6Arms @ max load

3.2.4 Leerlaufleistungsaufnahme bei UE /	115V AC, 230V AC : $\leq 0.5W$
Stand-by power consumption at UIn:	115V AC, 230V AC : $\leq 0.5W$

3.3 Ausgangsdaten / Output data:

Messaufbau siehe /	http://www.friwo.de
Measuring setup see:	

3.3.1 Ausgangsspannung /	UA: 12V DC +5% / -5%	UBr : $\leq 120mV_{ss}$
Nominal output voltage:	Uout: 12V DC +5% / -5%	UBr : $\leq 120mV_{pp}$

Ripple voltage test: 100nF ceramic capacitor and 22uF aluminum electrolytic capacitor should be parallel at output terminal, and the oscilloscope with 20MHz bandwidth is required.

3.3.2 Nennausgangsstrom /	IA : 5400mA
Nominal output current:	Iout : 5400mA

3.3.3 Wirkungsgrad /	
Efficiency:	$\geq 87\%$ (Energy Star level "V")

3.3.4 Ausgangs-Kurzschluss-Schutz / Output short protection

Bei kurzgeschlossenem Ausgang spricht der Kurzschlussschutz an. Nach Entfernen des Kurzschlusses arbeitet das Netzteil normal weiter.

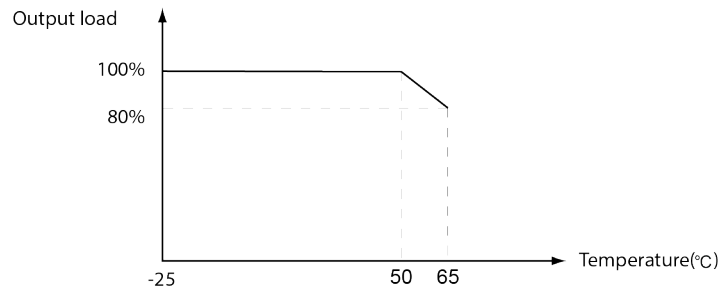
If the PSU output shorted, unit will enter bouncing, until the short circuit removed, PSU will work normally again.

3.4 Betriebstemperatur / Operating temperature

According to assembly drawing, the operation temperature:

-25 - +65°C (Vollast bis 50°C, danach lineare Abnahme der Leistung bis auf 80% bei 65°C)
-25 - +65°C (Full load to 50°C, derate linearly to 80% load at 65°C).

Output derating



3.5 Testanweisung / Instruction

Vor Inbetriebnahme des Netzteils unbedingt beachten: Mit dem Erdungssymbol gekennzeichneten Montagelöcher müssen durch einen genügend niederohmigen ($\leq 0,1 \text{ Ohm}$) Leiter dauerhaft verbunden werden. Dessen Eignung kann mit dem folgenden Test überprüft werden: Ein Strom von 25 A oder dem 1,5-fachen des Ausgangsnennstroms (je nachdem was jeweils höher ist $\pm 10\%$) wird aus einer 50 Hz oder 60 Hz Stromquelle, deren Leerlaufspannung 6 V nicht übersteigt, für 5s bis 10s durch die Montagelöcher geleitet, die bei fehlerhafter Grundisolierung spannungsführend werden könnten. Der Spannungsverlust zwischen beiden angegebenen Montagelöchern wird gemessen und die Impedanz aus dem Strom und dem Spannungsfall berechnet. Diese Impedanz soll 0,1 Ohm nicht überschreiten.

When use, the hole with "PE" symbol shall be connected by sufficiently low impedance ($\leq 0.1 \text{ ohm}$). Compliance is checked by the following test:

A current of 25 A or 1,5 times the rated current of the equipment, whichever is greater ($\pm 10\%$), from current source with a frequency of 50Hz or 60Hz with a no-load voltage not exceeding 6V is passed for 5 s to 10 s through the two screw holes which could become live in case of failure in basic insulation.

The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop. It shall not exceed 0.1 ohm.

4 Sicherheitsanleitung / Safety details:

Sicherheitsaufbau nach / Safety-standard acc. to :	EN60601-1, EN62368-1
Schutzklasse / Protection class :	N/A
Trennung (prim.-sek.) / Separation (prim.-sec.) :	Galvanisch durch Wandler Galvanic by transformer
Kriech- und Luftstrecken / Creepage distance and clearance :	$\geq$ Kr : 8mm, Lu : 5mm ; Cr : 8mm, Cl : 5mm
Betriebshöhe / Operating altitude:	$\leq$ 3000m
atmosphärischen Druck / atmospheric pressure :	$\geq$ 690hPa
Erdableitsstrom / Earth leakage current:	I Ableit: $\leq$ 500 μ A I leak: $\leq$ 500 μ A
Berührungsstrom / Touch current:	I Ableit: $\leq$ 100 μ A I leak: $\leq$ 100 μ A
Gemessen nach / According to : siehe / see www.friwo.de	EN60601-1
Hochspannungstest / High-voltage test :	Primary to secondary $\geq$ 4 KV AC; Primary to earth $\geq$ 1.5 KV AC; Secondary to earth $\geq$ 500V AC
Anwendungsbereich / Range of application :	Medizinische Anwendungen Medical applications
Umgebungstemperatur / Ambient temperature range :	-25°C bis / to +50°C, bis zu +65°C mit 20% Leistungsabsenkung / derate 20% load at +65°C

5 EU-Konformitätserklärung / EU Declaration of Conformity

Wir, der Hersteller, erklären hiermit, dass das Produkt: /
We, the manufacturer, hereby confirm, that the product:

Gerätetyp / Type: OF65M/12
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Zeichnungs-Nr. / Drawing-No.: 15.4312.500-00
weitere Merkmale / additional information:

mit der beiliegenden Beschreibung die Anforderungen der Niederspannungsrichtlinie 2014/35/EU, der EMV-Richtlinie 2014/30/EU und Öko-Design Richtlinie 2009/125/EG erfüllt.

Hiermit bestätigen wir, dass unsere Produkte, unabhängig von der Produktionsstätte, RoHS- konform produziert werden und die Anforderungen der EU-Richtlinie 2011/65/EU mit der harmonisierten Norm EN 50581:2012, einschließlich der delegierten Richtlinie (EU) 2015/863 zur Änderung von Anhang II der Richtlinie 2011/65/EU, erfüllen.

Der Kunde verpflichtet sich, mit der Anerkennung dieses Dokumentes, FRIWO im Falle eines Produktfehlers umgehend zu informieren.

with the enclosed description fulfils the requirements of the Low Voltage Directive 2014/35/EU, the regulations of the EMC Directive 2014/30/EU and the eco design Directive 2009/125/EC.

Hereby we confirm that our products, regardless of the production site, RoHS-compliant production and fulfill the requirements of the EU directive 2011/65/EU the harmonised standard EN 50581:2012, including the delegated directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU.

By signing this document customer confirms and warrants that in the event the product described herein shows any flaws or malfunction, customer shall inform FRIWO immediately of such flaw or malfunction.

Das Gerät entspricht der / The unit corresponds to:

- a) Niederspannungsrichtlinie / Low Voltage Directive :
EN 60601-1:2006/A12:2014, EN 62368-1
- b) EMV-Richtlinie / EMC Directive :
EN 55024:2010/A1:2015, EN 55032:2015, EN 60601-1-2:2015
- c) Öko Design / ECO Design :
not applicable

Ausstelldatum / Date of issue: 06.08.2020



ppa. Dominik Wöffen
Chief Operation Officer



i.A. Andreas Frehland
Head of Approval

6 Links & Miscellaneous

EMC-specification

6.1 Noise-suppressed: acc. to EN55024 ,55022/B and FCC part 15B.

Suggest that the length of output wire is not in excess of 0.5m

6.2 Harmonic current emissions ass.to IEC61000-3-2

6.3 Immunity to electrostatic discharge (ESD): acc. to IEC61000-4-2

Discharge characteristic	Test level	Assessment criteria Uin 120Vac	Assessment criteria Uin 230Vac
Air discharge	±8kV	B	B
Contact discharge	±6kV	B	B

6.4 Immunity to radiated electromagnetic field: acc. to IEC61000-4-3 Test characteristic: 80 - 2.5GHz; 80% AM (1 kHz)

Test level	Assessment criteria
10V/m	A

6.5 Immunity to fast electric transients (burst): acc. to IEC61000-4-4

Coupling	Test level	Assessment criteria Uin 120Vac	Assessment criteria Uin 230Vac
AC - input	±2kV	B	B

6.6 Surge capability: acc. to IEC61000-4-5

Surge voltage	Assessment criteria Uin 120Vac	Assessment criteria Uin 230Vac
±1KV(Line to line)	B	B
±2KV(Line to earth)	B	B

6.7 Power frequency(50/60Hz) magnetic field.acc.to IEC61000-4-8.

Test level	Assessment criteria
3A/m	A

6.8 Immunity to voltage dips, short interruptions and voltage variations.

Test acc. to IEC61000-4-11

Test performed at $U_{in} = 120V_{ac}/230V_{ac}$

Voltage dips

Test level %Un	Voltage dips and short interruptions %Un	Duration time of voltage Dips (in half sine)	Test result $U_{in} 120V_{ac}$	Test result $U_{in} 230V_{ac}$
0	100	0.5	B	B
		(5s)	B	B
40	60	5	B	B
70	30	25	B	B

6.9 Assessment criteria

- Agreed operational behaviour within the specified limits.
- Time limited functional diminishment of malfunction during the tests is permitted. The function is self-reactivated by the unit following completion of the tests.
- Malfunction is permitted. The function can be reactivated either by reconnection to the mains or by operator intervention.

7 Installation insctruction

7.1 Rating

Type : OF65M/12

Rated voltage : AC 100-240V

Nominal Current : Max 1.6A

Rated frequency : 50/60 Hz

Class : I

Protection against electric shock : By means of appropriate installation

Output voltages and currents DC12V/5.4A(SELV)

Max. ambient temperature for rated output power : 50°C

Max. operating relative humidity : 95%,no condensation.

Storage : -25to +85°C

Units should be allowed to warm-up under non-condensing conditions before application of power.

Remark : the end-use product shall provide an adequate enclosure to prevent access to the power supply and have an adequate enclosure for protection against the spread of fire.

7.2 Classification

Protection against electric shock = Class I,mains grounded input (protective earth must be connected to mains supply network).

Protection against moisture:

Have not been evaluated for use in the presence of a flammable anaesthetic mixture with air,oxygen,or nitrous oxide.This evaluation is to be made on the end equipment by the OEM.

Do not connect as direct power source to patient circuits.

Not to be used as single power source within critical life support systems,without prior request to FRIWO Geratebau GmbH and receipt of confirmation in writing from FRIWO Geratebau GmbH.

Ask for Application Engineering Support from FRIWO Geratebau GmbH.

7.3 Temperatures

The maximum operating temperatures of certain safety components, as defined in the applicable safety standards, must not be exceeded after installation to preserve the intended safety.The output power,ambient air temperature and the availability,amount,direction and/or restriction of airflow influence the temperatures of these components.

8 Explanation of symbols

EXPLANATION OF SYMBOLS	
	Alternating Current
	Direct Current
	Attention, Consult Accompanying Documents
	Attention, Dangerous Voltages
	Earth (Ground)

8.1 Fusing

Fuses for both Line and Neutral are provided in the power supply. Replace only with same type and rating of use.

8.2 Caution

Read instruction manual before connecting to mains.

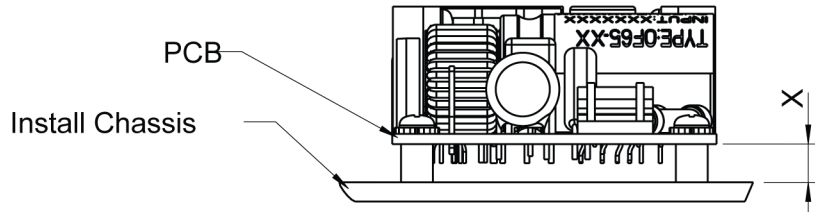
8.3 Warning! Risk of fire!

A blown internal fuse is an indication of catastrophic failure of circuit component(s). Refer to fuse marking on the supply for rating.

8.4 Warning! Shock Hazard!

Dangerous voltages are present on some components, printed wiring traces and heatsinks.

9 Installation Method



Distance from the chassis to PCB:

Type 1. The install chassis is insulative

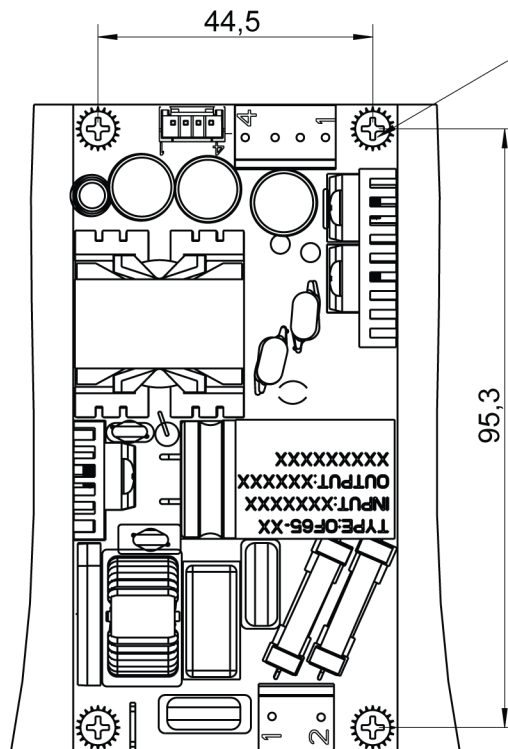
$X \geq 3.0\text{mm}$

Type 2. The install chassis is metal

$X \geq 6.0\text{mm}$

Type 3. The install chassis is metal

$X \geq 3.0\text{mm}$ And shall be add a insulation slice between PCBA and metal chassis



The screw head shall be less than 7mm