

SPECIFICATION FOR APPROVAL

MODEL NUMBER	HDP12-MD05024U
PART NUMBER	HDP12-MD-WUSB-4
DESCRIPTION	I.T.E. & MEDICAL POWER SUPPLY WHITE
CUSTOMER / PROJECT CODE	MED-02
REVISION	A1 (Preliminary)
DATE	August 27, 2018

CUSTOMER APPROVAL	DATE
SEACOMP ENGINEERING APPROVAL	DATE

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Revision History

REV	DESCRIPTION	DATE
A0 (Pre)	Initial Release	Apr 16, 2018
A1 (Pre)	Updated Ripple and Noise from "100mVp-p" to "120mVp-p" in section 3.2.4	Aug 27, 2018
	Updated pad print artwork in section 6.2	
	-	

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1 Scope

The device is a 12-watt AC to DC adapter designed to provide a constant power source for electrical products. This adapter is certified for both medical and informational technology equipment (ITE) applications.

2 Quality Requirements

2.1 Product Specific Quality Requirements

2.1.1 Mechanical / Electrical Requirements

2.1.1.1 Paint and Print Test

In accordance with EN 60068-2-70

The printings have to withstand the testing procedures without any restrictions.

Test liquid	Mineral oils (example: Baby oil)
Wiping cycles	1,000
Contact pressure	1N ±0.2N

2.1.1.2 Mechanical and Electrical Reliability

All electrical contacts and mechanically moving parts have to withstand a stress test of at least 3,000 simulated connecting cycles without any damage. After the test, the device must have 100% functionality. Connectors must comply with the manufacturer's requirements or relevant standards at minimum.

2.1.1.3 Cable Tension and Flex

All cable joints and strain relief points have to pass the following:

Static load:	5Kg / 1 min at 0 degree and at 90 degree angles
Flex test:	+/- 60 degree bending angle 250gm at 20cycle / minute with a minimum
	speed of 1000 cycles.

2.1.1.4 Drop Test

This test requires the device to be dropped from a height of 1 meter onto a concrete floor. The drop should cover all surfaces including the 2 edges and all 4 corners. After the test, the device should have 100% functionality. There should not be any cracks, breaks or damage to any surface or have any loose internal components. Additionally, the ultrasonic weld joint should still be intact with minimum 80% coverage.

2.1.1.5 Enclosure Crush Test

This test applies a uniformly distributed weight of 250 Newtons on all surfaces for 5 seconds per surface. There should be no physical damage or effect on the products performance (i.e. operating folding AC blade, easy insertion of international adapters, snug USB connector fit).

2.1.1.6 Cable Burn Test (to be tested by safety lab)

In accordance with DIN 75200

Burn down speed max. 50 mm/min

UL rated cable with UL file is an acceptable replacement for this test. Cable to be VW-1 rated.



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2.1.2 **Climate Requirements**

2.1.2.1	Temperature Range	
	Full Functionality	0°C up to +45°C
	Storage Temperature	-20°C up to +85°C

2.1.2.2 Thermal Shock (operational)

Thermal Onock (oper	
Low Temperature	0°C (AC/DC)
High Temperature	50°C (AC/DC)
T/t	15°C/min
Cycle Duration	1 hour
Number of Cycles	10
Mode of Operation	Minimum 75% full load
Requirement	100% functionality after test, without any damages or physical change

2.1.2.3 Thermal Aging

Temperature	-20°C and +85°C
Duration	96 hours at each temperature
Mode of Operation	Power off
Requirement	100% functionality after test, without any damages or
	physical change

2.1.2.4 Humidity (non-condensing)

Temperature	+45°C
Humidity	95%
Duration	96 hours
Mode of Operation	Power up no load
Requirement	100% functionality after test, without any damages or physical change

2.1.2.5 Humidity (condensing)

	5/
Upper Temperature	+45°C
Lower Temperature	+25°C
Humidity	95%
Test Cycle	5°C / max ramp rate
Duration	96 hours
Number of cycles	6
Mode of Operation	Non Operational
Requirement	100% functionality after test, without any damages or physical change

2.1.2.7 Salt Spray Follow ASTM B117 standard with the possible exceptions listed below.

Temperature	35°C + 1.1 / - 1.7°C
Salt Solution	5%+/-1 Salt solution (NaCl) in Distilled or D1193 Type IV water
PH	6.5 - 7.2
Fog Rate	1m - 2 mL / hr / 80sq.cm
Duration	24 hours



2.2 General Quality Requirements

2.2.1 Product Related Requirements

2.2.1.1 General Appearance

Follows cosmetic requirements listed in Section 4 of this specification.

2.2.1.2 Emissions

The device must not produce any nuisance or unhealthy smell. A certificate must be made available proving the use of harmless materials.

2.2.1.3 Product Safety

The product has to comply with the relevant requirements listed in IEC 60950 (ITE) and IEC 60601 (medical).

Normal usage of the product must not result in any danger. In particular, any broken component parts, including electric components, may not result in any risk or danger of injury to the user. This is to be proven by a risk analysis during the product's development phase. Any potential hazard has to be indicated clearly in the user manual.

During normal use at an ambient temperature of 25°C, the housing (made of synthetic material) may warm up by 50K. Therefore, the maximum temperature of the parts could be as high as 75°C.

Individual "Hot Spots" (maximum size of 2 cm²) is acceptable if they are not located in the grip area. A warm up by 60K is acceptable in these "Hot Spots." Therefore, the maximum temperature of these parts could be 85°C.

For both normal use and "Hot Spot" instances, the housing must not exceed the maximum temperature of the applied synthetic.

When using tantalum capacitors, the effects of a potential explosion must be reduced to prevent any hazard to the user's health.

Protective actions against confusing the poles of the electric connectors have to be taken for any internal parts or connectors with specific polarity.

Transportation, storage, and operation of the adapter must not create any hazard, personal injury or any material damage. This is guaranteed through the controllable quality of workmanship and material used.

It must be guaranteed that after contact with natural oils, the housing material's performance does not result in any dangerous situations to the customer.



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2.2.1.4 Recycling and Environmental Compatibility Must comply with RoHS and REACH.

Quality Level, (AQL) In accordance with DIN ISO 2859 Part 1

General test-level	II
Critical defects	AQL 0
Major defects	AQL 0.4
Minor defects	AQL 0.65

2.2.2 Supplier Related Requirements

2.2.2.1 Demonstration of Quality

The supplier is obliged to maintain a quality assurance system which covers R&D and production specific items. This system must meet the requirements of ISO 9000-2008. A quality assurance plan (QA plan) is required for a project-specific proof of quality-assuring measures. The plan should be made available and presented upon request.

For the development phase, the QA plan needs to define milestones as proof of the reliability prognoses. The development results and the release by the customer need to also be included in this plan.

For the production phase, the QA plan has to focus on the detailed verification of all the planned QA steps from component procurement to delivery. Any acceptance or error criteria to be applied to the QA plan must meet the process capability index as defined in this specification.

2.2.2.2 Process Assurance

The quality capability has to be proven by a process capability of Cpk > 1.33 and must be documented by a continuous monitoring of the production process. Parameters relevant for this process capability will be marked separately in the product's construction documents.

2.2.2.3 Reliability

The probability of failure and the return of devices for repair must be less than 1% per year. The failure rates have to be predicted using MTBF calculations. The MTBF calculations have to be proven and available to the customer upon request.

A minimum of 50k MTBF must be achieved under nominal load and 25°C ambient temperature.

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3 Electrical Characteristics

3.1 Input

- 3.1.1 Input Voltage Nominal: 120/220 VAC
- 3.1.2 Input Voltage Range: 90 ~ 264 VAC
- 3.1.3 Input Frequency Range: 50 / 60Hz (47 ~ 63 Hz)
- 3.1.4 Inrush Current: 50A peak at 240AC input < 200us
- 3.1.5 Maximum Input Current: 0.35A measured at 12 Watts
 - Vin = 100VAC & 2.4A load
- 3.1.6 Efficiency: CEC-VI
- 3.1.7 Turn-on Time: < 2s
- 3.1.8 Input Fuse: 2A / 250VAC standard blow
- 3.1.9 AC Input Receptacle Type: Folding US AC blades
- 3.1.10 Isolation Voltage: Meet IEC 60950, IEC 60601
- 3.1.11 AC Leakage Current: .15mA measured 264V & 63Hz
- 3.1.12 Dielectric withstands Voltage: 3000VAC 60sec or 4242VDC 60 sec with no breakdown;

Earth leakage at 110% of rated voltage should be < 10mA

3.1.13 Input Power (No Load): < 0.1W

3.2 Output

- 3.2.1 DC Output: 5.0 VDC
- 3.2.2 Output Current: 2.4A
- 3.2.3 Load Regulation: 4.75-5.25 VDC
- 3.2.4 Ripple and Noise: 120mVp-p
- 3.2.5 Turn-on Overshoot: < 10%
- 3.2.6 Over-current Protection: 3A max
- 3.2.7 Short Circuit Protection: Protected for continuous short circuit
- 3.2.8 Reset After Shutdown: Yes
- 3.2.9 Thermal Stability Time: 30 min
- 3.2.10 Peak Load Duration: Indefinite (OCP will prevent overload)



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3.3 Cable & Connector

USB-A Connector with Bridge configuration: D+/D- shorted.



4 Pin Male "A" Connector on the cable



4 Pin Female "A" Connector on the computer



4 Pin "B" Male Connector on cable



4 Pin "B" Female Connector on computer

Pin	Name	Description	Color
1	VCC	+5 VDC	Red
2	D-	Data -	White
3	D+	Data +	Green
4	GND	Ground	Black

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4 Cosmetic

4.1 Surface Definitions

Level A is the primary surface. For example, the front face of the adapter.

Level B is a secondary surface that may be viewed periodically by the end user, but is not in direct view during normal use. For example, the Cable (AC and DC), the sides of the housing, and the back of the housing.

Level C surfaces are not visible by the end user. For example, the inaccessible inside surfaces of the product.

4.2 Inspection Conditions

- 4.2.1 Inspection Method: Light source: Cool white fluorescent lamp 750 1000Lux
- 4.2.2 Viewing Distance: 30cm
- 4.2.3 Viewing Angle: 0 90 Degrees
- 4.2.4 Part Rotation Angle During Inspection:
 - Vertical Rotation Angle 180 Degrees
 - Horizontal Rotation Angle 360 Degrees
- 4.2.5 Viewing Time:
 - 5 seconds total for all surfaces



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4.3 Cosmetic Defect Definitions

Defect	Level A	Level B	Level C	
Scratches, Dents, and Burrs (see Note 1)	Single defect not exceeding total surface area 5.50 mm ²	Two defects not exceeding total surface area 11 mm ²	Accept if it does not affect fit or function	
Hairline Scratches, Gate Blush/Trim, Stress	Use 25% Contrast Standard to accept or reject for visible hairline scratches with depth of < 0.1 mm (total surface area not to exceed limits set in surface scratch below)			
Surface Scratches, Scuffs (see Note 1)	Single defect not exceeding total surface area of 5.7 mm ²	Two defects not exceeding total surface area 25 mm ²	Accept if it does not affect fit or function	
Chips, Nicks, Cracks or Broken Features	Not Allowed			
Flash, Burrs, Sink Marks (see Note 2)	Not Allowed	Less than 0.5mm	Accept if it does not affect fit or function	
Discoloration	Follow color samples			
Parting Lines	See diagram			
General Stains (not permanent)	Not allowed			
Rust	Not allowed			
Printing	No missing text or mistakes allowed. All letters should be visible. Refer to approved sample.			

Note 1:

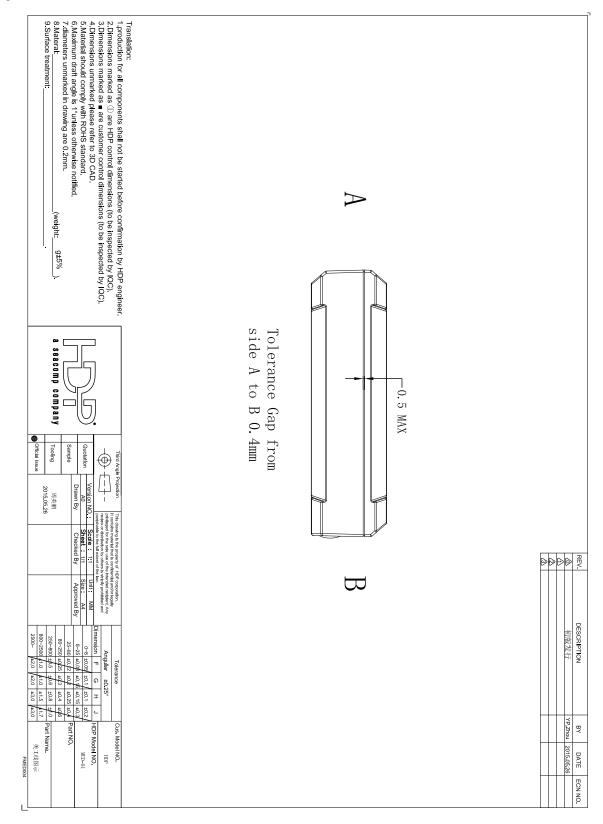
Area called out in these fields are calculated based on limit samples. The values are calculated based on average area covered by the features.

Note 2:

DC over-mold flash marks have to be signed off on samples and provided as acceptable limits.

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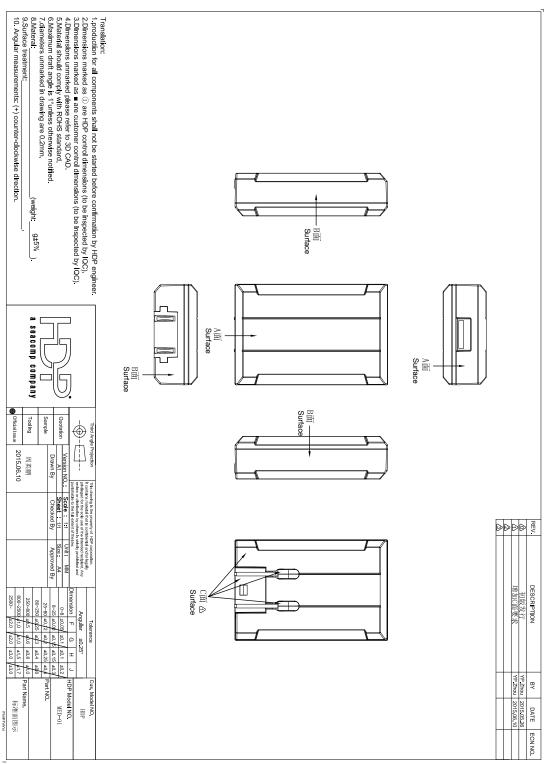
Parting Line



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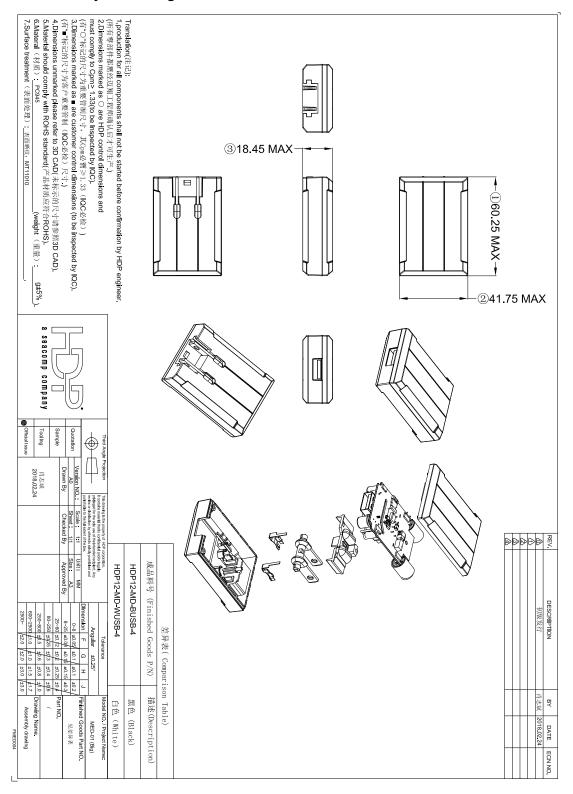
4.3

Size / Weight Product size should be 41.75W X 60.25L X 18.45H mm. Product weight is 45gm (weight and size including bracket).



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4.4 Assembly Drawing



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Electromagnetic Compatibility The following tests are required: 5

Power Conversion Device	EU Reference	Title of Standard	International Reference	Test Level for Heavy Industrial	Test Level for Light Industrial	Test Level for 48 VDC p/s
AC-DC, DC- DC, Power Supplies	EN55022:1998 To be soon updated to EN55022:2006	Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement	CISPR22:1997	Class "B" 4dB of margin Class "A" or Class "B" for servers	Class "B" 4dB of margin Class "A" or Class "B" for servers	Class "B" 4dB of margin Class "A" or Class "B" for servers
DC-DC, DC- DC Power Supplies	EN55024:1998 (EN50082-2:1995 updated to EN61000-6- 2:2001 for -48 VDC supply)	Information technology equipment – Immunity Characteristics – Limits and methods of measurement	CISPR24:1997			Different tests and limits for DC power supplies
AC-DC, AC- DC Power Supplies	EN61000-3-2:2000 (PFC Power Supplies ONLY if rated greater than 75W)	Electromagnetic Compatibility (EMC) – Part 3: Limits – Section 2: Limits for harmonic current emissions (Equipment input current up to and including 16 A per phase)	IEC 61000-3- 2:2000	Must meet Class D requirements	Must meet Class D requirements	N/A
AC-DC, AC- DC Power Supplies	EN61000-3-3:1995 (PFC Power Supplies ONLY)	Electromagnetic Compatibility (EMC) – Part 3: Limits – Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current up to and including 16A	IEC 61000-3- 3:1994	Meet specification	Meet specification	N/A
AC-DC, DC- DC, Power Supplies	EN61000-4-2	Electromagnetic Compatibility (EMC) – Part 4: – Section 2: Electrostatic discharge immunity test	IEC 1000-4-2	(+/-) 2, 4, 8, 12 and 15 kV air (+/-) 2, 4, 6, 8 kV contact discharge	(+/-) 2, 4, 8, 12 and 15 kV air (+/-) 2, 4, 6, 8 kV contact discharge	(+/-) 2, 4, 8, 12 and 15 kV air (+/-) 2, 4, 6, 8 kV contact discharge
AC-DC, DC- DC, Power Supplies	EN 61000-4-3 + Israeli Deviations in SI 961 part 6.2	Electromagnetic Compatibility (EMC) – Part 4: – Section 3: Radiated, radio-frequency electromagnetic field, immunity test	IEC 1000-4-3 Basic Standard ENV 50140	10V/m 80-1000MHz, 80% AM 900 +/- 5MHz 50%, 200Hz	3V/m 80-1000MHz, 80% AM 900 +/- 5MHz 50%, 200Hz	10V/m 80-1000MHz, 80% AM 900 +/- 5MHz 50%, 200Hz
AC-DC, DC- DC, Power Supplies	EN 61000-4-4	Electromagnetic Compatibility (EMC) – Part 4: – Section 4: Electrical fast transient/burst immunity test	IEC 1000-4-4	1, 2, 4kV – Power 0.5, 1, and 2kV – Signal	1, 2 kV – Power 0.5, 1 kV – Signal	1, 2 kV – Power 0.5, 1, and 2kV – Signal
AC-DC, DC- DC, Power Supplies	EN 61000-4-5	Electromagnetic Compatibility (EMC) – Part 4: – Section 5: Surge Immunity Test	IEC 1000-4-5	1, 2kV differential 2, 4kV common	0.5, 1 kV diff. 0.5, 1, 2, 2.5 common	0.5, 1kV differential 0.5 1kV common
AC-DC, DC- DC, Power Supplies	EN 61000-4-6 + Israeli Deviations in SI 961 part 6.2	Electromagnetic Compatibility (EMC) – Part 4: – Section 6: Conducted disturbances induced by radio- frequency fields – immunity test	IEC 1000-4-6 Basic Standard ENV 50141	10V/m 80% AM (1kHz)	3 V/m 80% AM (1kHz)	10 V/m 80% AM (1kHz)
AC-DC, DC- DC, Power Supplies	EN 61000-4-8	Electromagnetic Compatibility (EMC) – Part 4: – Section 8: Power-frequency magnetic field immunity test	IEC 1000-4-8	30 A/m (r.m.s.)	1 A/m (r.m.s.)	30 A/m (r.m.s.)
AC-DC, DC- DC, Power Supplies	EN 61000-4-11	Electromagnetic Compatibility (EMC) – Part 4: – Section 11: Voltage dips, short interruptions and voltage variations immunity test	IEC 1000-4-11	30% for 0.5 S >95% for 10mS >95% for 5 S	30% for 0.5 S >95% for 10mS >95% for 5 S	30% for 0.5 S >95% for 10mS >95% for 5 S

Light Industrial: EN55022:1998 (Emission) and EN 61000-6-1:2001 (Immunity) Heavy Industrial: EN55011 (Emission) and EN 610006-2:2005 (Immunity) The content of the test report, at a minimum, includes:

- Test object used (development status with serial number/sample name) .
- Mode(s) of operation of the test object .
- Test result .
- Photograph/sketch of the test environment along with listed test conditions .
- Applied measurement tools/equipment
- Ambient temperature for ESD-tests. Also include air pressure and air humidity
- Name of Test Engineer
- Date of the test

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6 Labeling

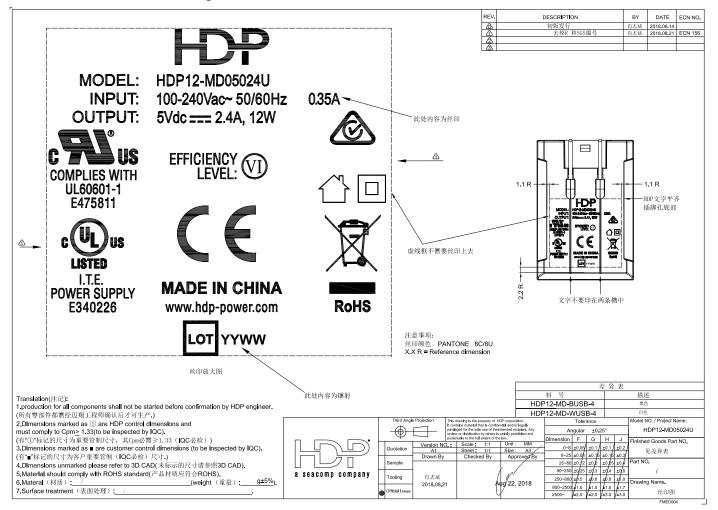
6.1 Labeling the Device

The labeling must comply with IEC 60950 and IEC 60601 requirements.

The following information as a minimum must be printed on the adapter:

Input rating Output rating Made in China Model and/or part number Production lot or date code

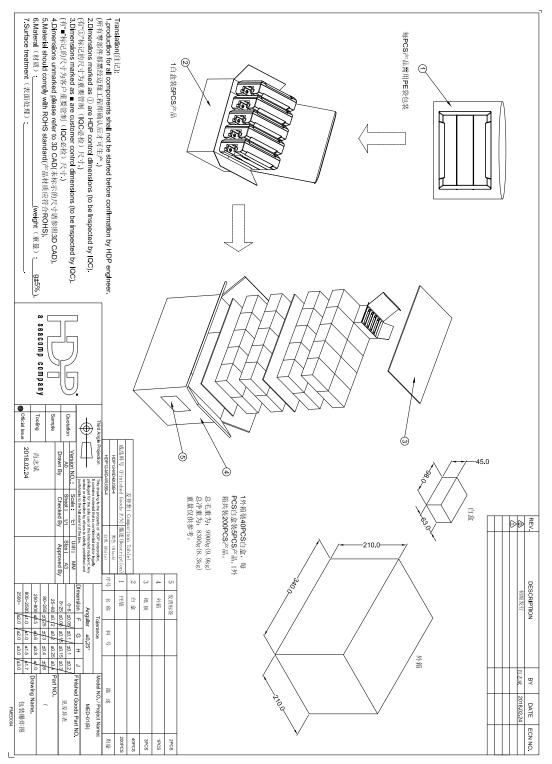
6.2 Label Drawing



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7 Packaging

7.1 Drawing





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Packaging Test 7.2

1	Bulk product	 Drop package on each side for a total of 10 drops (2 opposite corners, 3 adjacent sides of bottom corner, then all 6 faces) per system on concrete floor from a height of 1.0 meter. This is an operational test. Pass/Fail Criteria: 1.The systems shall pass Functional Test. 2. No visible damage to product and gift box.
2	Drop test for Packaged Product (gift box, clamshell, etc.)	 Drop fully packaged products (in gift box or clamshell) onto a concrete floor from height of 153cm for 10 drops on the six surfaces and four corners. Pass/Fail Criteria: The systems shall pass Functional Test. Paper or PET deformation is acceptable. No damage in product integrity of packaging materials (e.g. sealed edge openings) is allowed.
3	Sinusoidal Vibration	Test with sine wave that will sweep the frequency from 7 - 500 hertz for construction test; 5 - 70 hertz for packaging test. Displacement >3.15mm. Total test duration time shall be 30 min (10 min per axis). Test shall be performed in three mutually perpendicular axes: Z-axis (vertical), Y-axis (fore-aft), and X-axis (lateral). Pass/Fail Criteria: The UUT and packaging shall withstand the above test procedure without visible damage or performance decline during operation.

8

Warranty One year warranty for defects arising from workmanship and materials per the SEACOMP Warranty, RMA, and Failure Analysis Policy.