

中检集团
INTERNATIONAL INSPECTION (SUZHOU) CO., LTD.



中检集团下属实验室
MEMBER OF CIC GROUP

62368 (Ed. 2) (Ed. 3)

中检集团下属实验室 中检(苏州)国际检验有限公司

62368 (Ed. 2) (Ed. 3)



CONTENTS

03

05 PSE J62368-1(H30)

06 CISPR152018 CISPR152013+A12015

07

10

11

12

13 62368(Ed.2) (Ed.3)

14 2018

16 A2LA

17

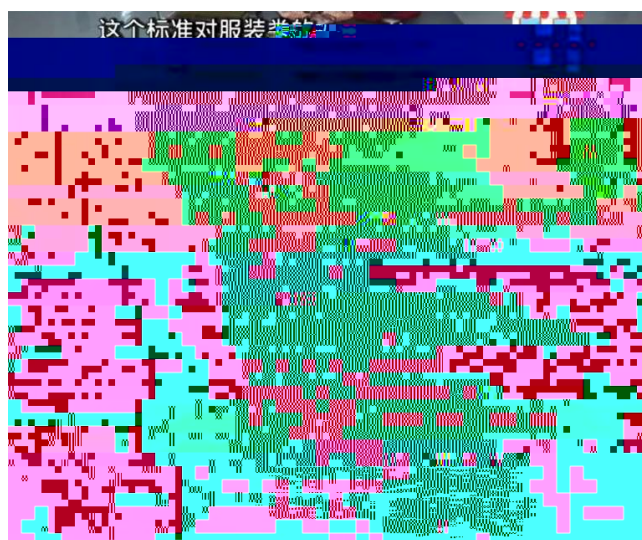
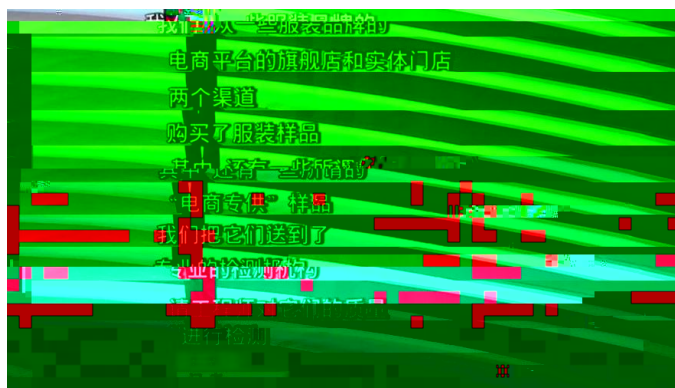
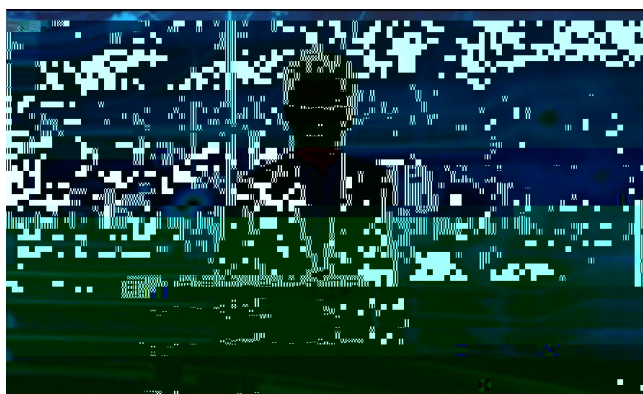
19

ICMD CMEF

20







PH

PSE J62368-1(H30)

PSE METI 2018 7 20

J62368-1(H30)

IEC 62368-1: 2014

IEC 62368: 2014

CISPR152018 CISPR152013+A12015

2018-05-15

CISPR 15:2018 Edition 9.0

CISPR15:

2013+A1:2015



300 MHz 1 GHz

CDNE

CDN

- CDNE EUT 30 MHz
- CI SPR 16-2-1 EUT
- CDNE EUT 3 m x 1 m x 1 m x x
- A:

- Table 2 3.
- a Control terminal s
- b

- Table 5 6.
- a Load terminal s
- b

- secti on4. 5 and 5. 3. 4

GU10

LED/CLED

EUT

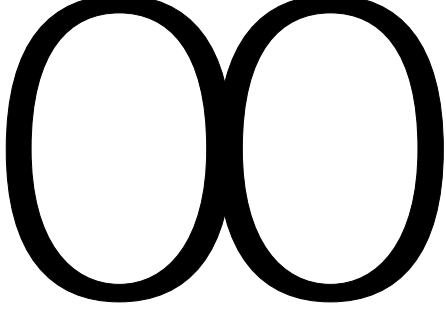
7. 8

1. 6m

CI SPR 14-1

60cm

3m



/ N/cm 10mm

905 v 20
5 60mmf 50 .

/mm
10.0
20.0 5.0

30

40

a) /
b) 3mm /N
c) 20mm

GB/T 1002-2015

/mm
e 10.0
14.0

40mm

30mm

a 230mm
b GB/T 20991-2007
8.4.1 30N
45°
c 70mm
d 25mm

a 25mm
b 10mm 1000
25mm
c 50 A 100 700

5.0

70

30
40
30

GB/T 2955-2017

20.0

3

5.0mm
25mm

m 4.0mm

20.0mm

8.0mm

25.0 mm
mm

10.0

70

20

5.0mm

GB/T 15107-2013

5.0mm

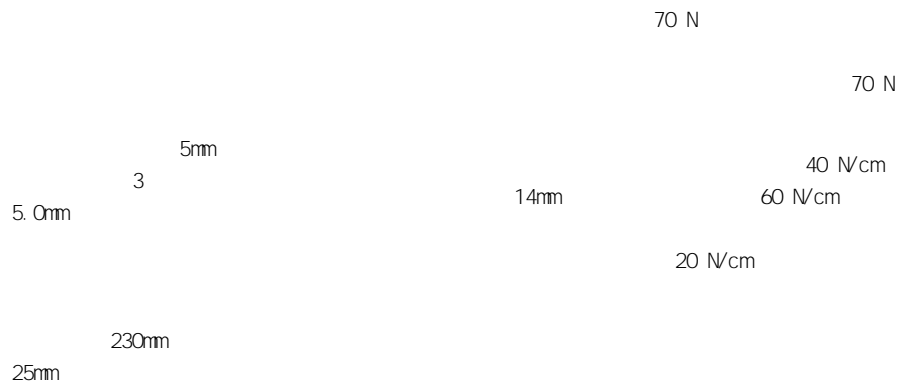
3

5.0mm

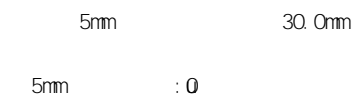
230mm

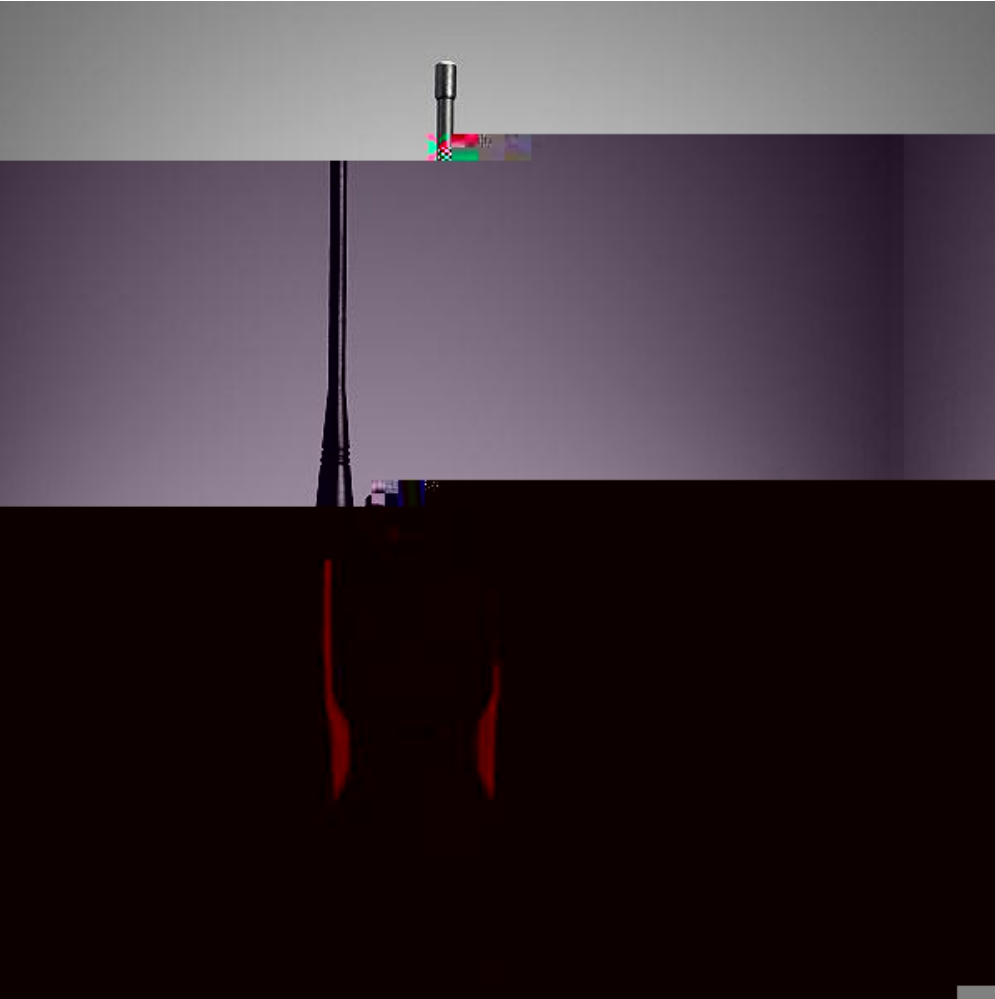
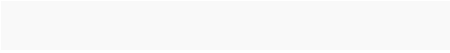
QB/T 4329-2012

GB/T 4331-2012



GB/T 2880-2016

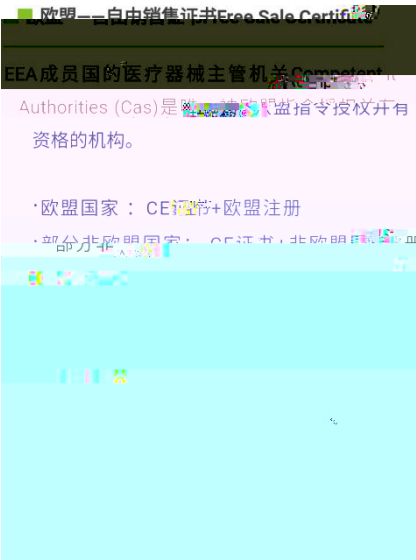




■ 欧盟——自由销售证书Free Sale Certificate

EEA成员国的医疗器械主管机关Competent Authorities (Cas)是欧盟指令授权并有资格的机构。

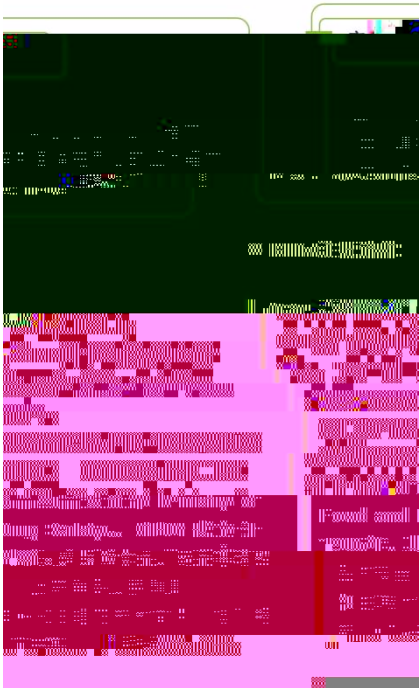
- 欧盟国家：CE证书+欧盟注册
- 部分非欧盟国家：CE证书+非欧盟国家注册



■ 韩国——KFDA注册

韩国卫生福利部 (Ministry of Health and Welfare, MHW)

监管部门：韩国卫生福利部 (Ministry of Health and Welfare, MHW)



▼ PMDA注册流程：

- 确定产品分类 (I,II特殊控制, II类控制,III,IV) 和产品JMDN 编码, 选择日代MA
 - 制造商向PMDA注册工厂;
 - II类特殊控制产品: 提交技术文件(PCB)
- 

1.



2.



3.



4.



62368(Ed.2) (Ed.3)

2018 10 4 I EC 62368-1: 2018 (Ed. 3) I EC 62368-1: 2014(Ed. 2) I EC 60950-1 I EC 60065
I EC (TRF) 2019 6

2020 12 20

ENV/UL 60950-1 ENV/UL 60065 EN 62368-1(2 0) UL/CSA 62368-1(2 0)
ENV/UL 60950-1 ENV/UL 60065 EN 62368-1(2 0)

2018

2018 6 27

2018

[2018 7]

CNAS L1225



2017 43

[2018 7]

61% 62%	
%	



DEHP DBP BBP DI NP DI DP DNOP

[2018 7]

http://jiangmen.customs.gov.cn/shenzhen_customs/511686/511688/511689/1927124/index.html

A2LA

10 17 -19 David Zimmerman

A2LA

David



A2LA

American Association for Laboratory Accreditation

ILAC

AAAL

A2LA

(International Laboratory Accreditation Cooperation)

ILAC

CNAS/

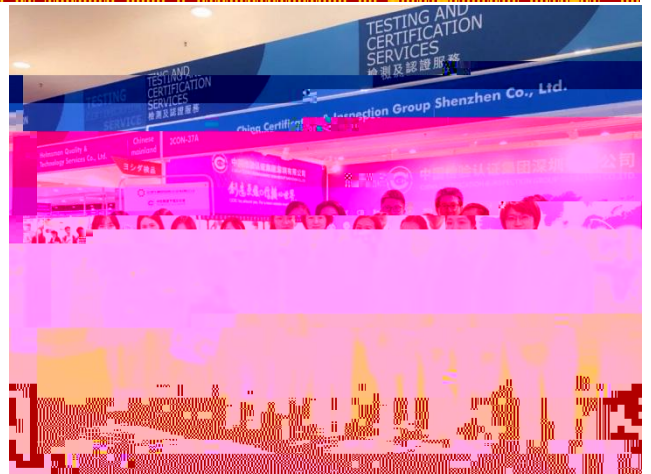
CNAL

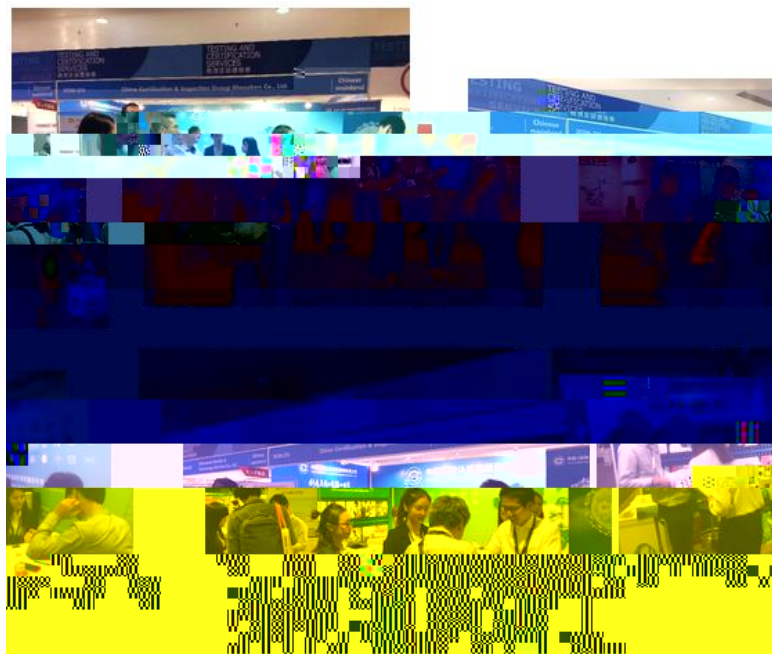
MRA

2018

2018 13 -16

7500





CMEF
ICMD

