



IEC 60601-1 GB9706



97\* \$\* \$%% ; 6- +\$\*

8 17 18

IEC60601-1 GB9706  
IEC60601-1 GB9706





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.....



# 9A 7 MM\$) \$) .&\$%&

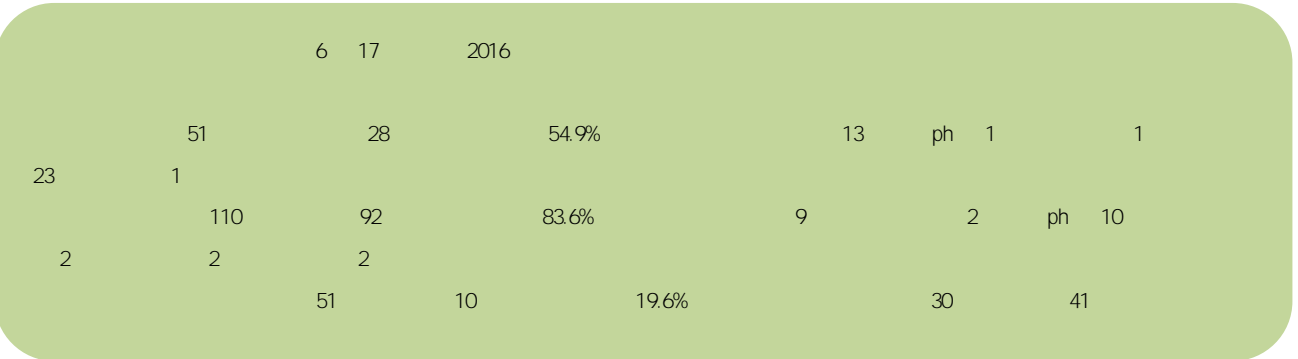
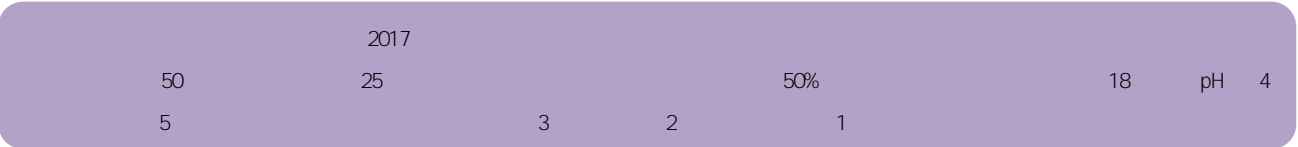
8 25

EMC YY0505:2012

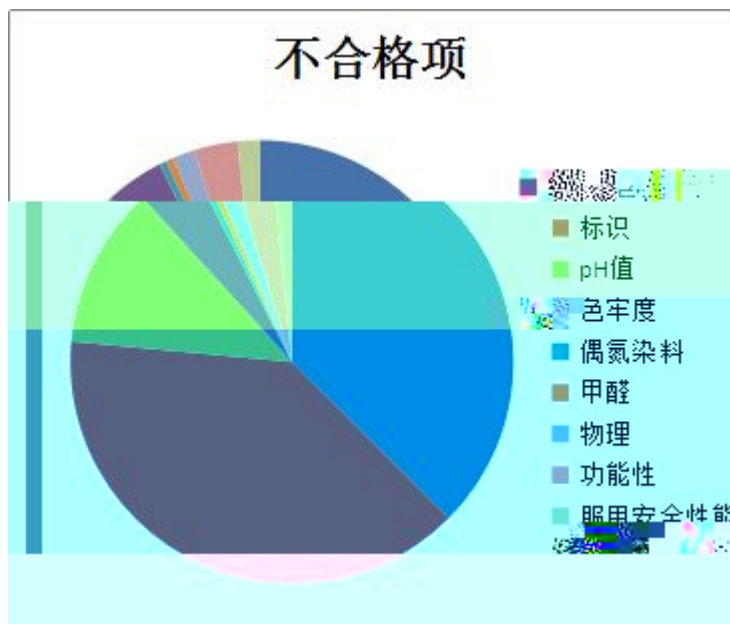
..

- ①
- ② EMC
- ③ EMC
- ④ EMC
- ⑤ EMC

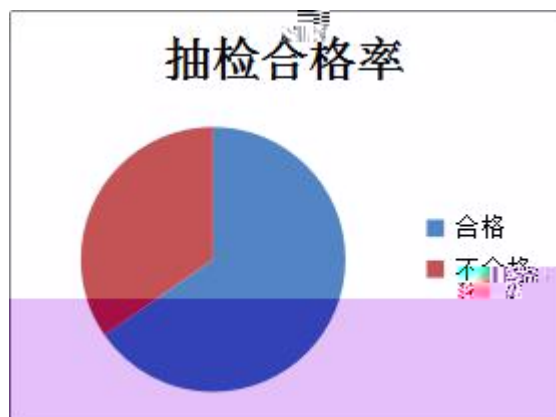
EMC



## 不合格项



## 抽检合格率



73

70

pH 22

22

346

226

65%

120

1.

2.

3.

4.

1.

100%

2.



	T	GB T 22849-2014	FZ/T 73026-2014	FZ/T 81004-2012
FZ/T 81006-2017	GB/T 2660-2017		FZ/T 81007—2012	FZ/T 73020-2012
GB 18401-2010A/B/C		GB 31701-2015A/B/C	"	"

pH

pH

: 85

&\$%

8	29	FDA	2018	2017	10	1	2018	9
30								
1		FDA 510k	USD4690	10542 USD				
2		FDA 510k	USD2636					

[FY 2018 Medical Device User Fee Small Business Qualification and Certification - Guidance for Industry, F](#)



2017 8 15

14

2017 38

2017 8 16

2021 1 1

2%

2%

0.0001%

0.0005%

2011

2013

20

2011

2013

30

5

60

5

40

40

10

500

3.5

>500

1500

5

>1500

13

2011

2013

2010 2

2026 1 1



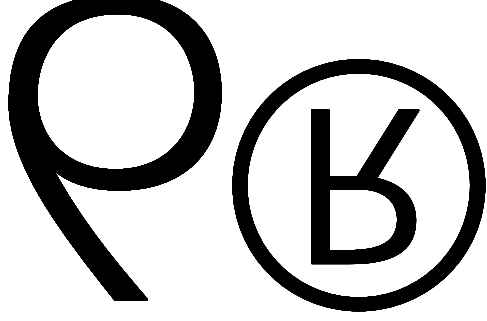
2017 5

(EU)2017/852

2017 8 8

2019 1 1

2017 3



2017 2

STB 1 66 2016 979 849

U

STBEE

2017 9 1

# UNIQUE

9B )) \$' )

EN 55035

EN 55020 EN 55024

EN 55020 EN 55024

EN

55035

EN 55035

EN 55020(AV)

EN 55024(ITE)

EN 55035

EN 55035

EN 55020

EN 55024

EN 55035

EN 55020 EN 55024

ESD ( )

EN 55035 +/- 4KV for Contact discharge +/- 8KV for Air discharge

EN 55020 +/- 4KV for Contact discharge +/- 8KV for Air discharge

EN 55024 +/- 4KV for Contact discharge +/- 5 /

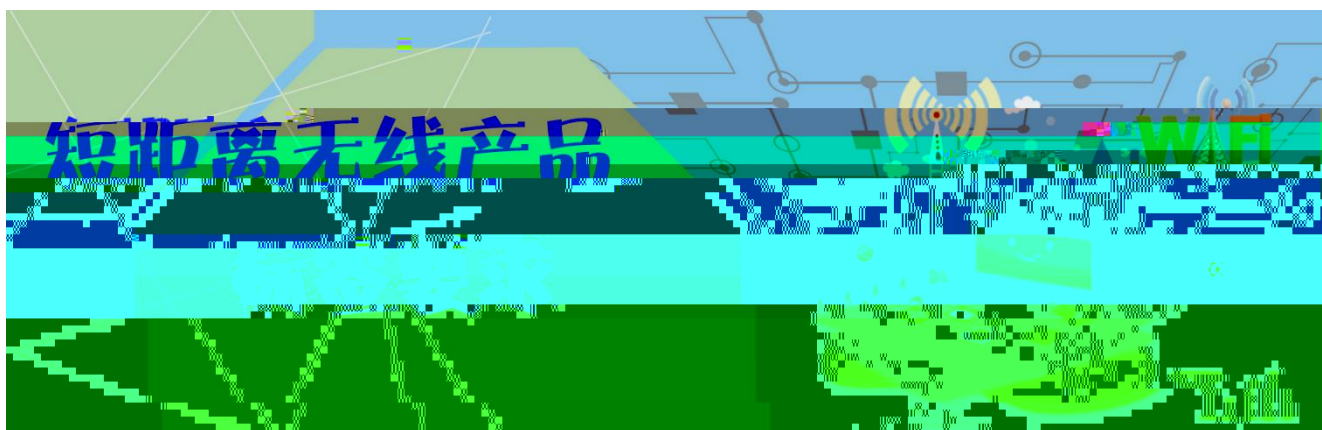
6. Voltage Dips & short interruptions( ) - Voltage dips
- |          |                       |  |  |
|----------|-----------------------|--|--|
| EN 55035 | Residual voltages <5% | Number of cycles: 0.5; Residual voltage: 70% | Number of cycles: 25 for 50Hz, 30 for 60Hz |
| EN 55020 | N/A                   |  |  |
| EN 55024 | Residual voltages <5% | Number of cycles: 0.5; Residual voltage: 70% | Number of cycles: 25 for 50Hz, 30 for 60Hz |

7. Voltage Dips & short interruptions( ) - Voltage interruptions
- |          |                       |  |
|----------|-----------------------|--|
| EN 55035 | Residual voltages <5% | Number of cycles: 250 for 50Hz, 300 for 60Hz |
| EN 55020 | N/A                   |  |
| EN 55024 | Residual voltages <5% | Number of cycles: 250 for 50Hz, 300 for 60Hz |

EN 55035

1. Broadband impulse noise disturbances, repetitive ( ) - Impulse Frequency Test Level  
 0.15MHz to 0.5MHz 107dBuV; 0.5MHz to 10MHz 107dBuV to 36dBuV; 10 to 30MHz 36dBuV to 30dBuV
2. Broadband impulse noise disturbances, isolated( ) - Impulse Frequency Test Level  
 0.15MHz to 30MHz 110dBuV

fX % c % % % \_



Label					
SRR					

SRRC

Label



\* =20mm\*30mm

CE

Label



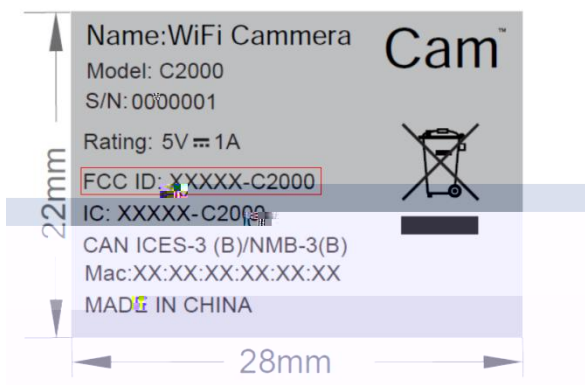
FCC ID

Label

Label

This device

complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.



IC

Label

Label

CANICES-3

(B)

This device complies with Canada Industry Licence-exempt RSS standard(s). Operation is subject to the following two conditions:

- (1) this device may not cause interference; and
- (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme aux CNR exemptes de licence d'Industrie Canada. Son fonctionnement est soumis aux deux conditions suivantes :

- (1) Ce dispositif ne peut causer d'interférences ; et
- (2) Ce dispositif doit accepter toute interférence, y compris les interférences qui peuvent causer un mauvais fonctionnement de l'appareil.



RCM

RCM

NXXX

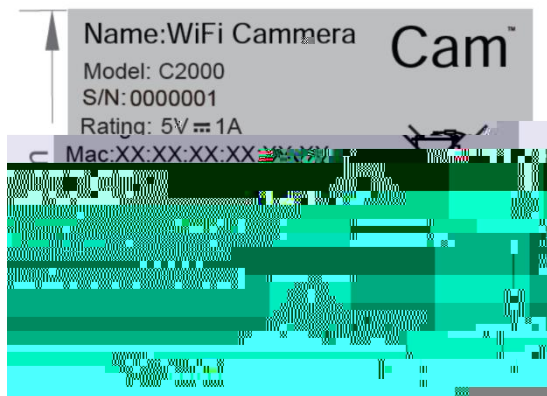
EN AS/NZS

RCMSDoC

SDoC

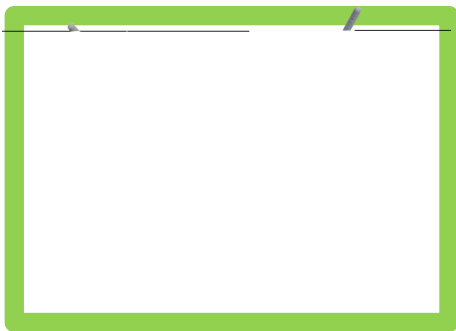
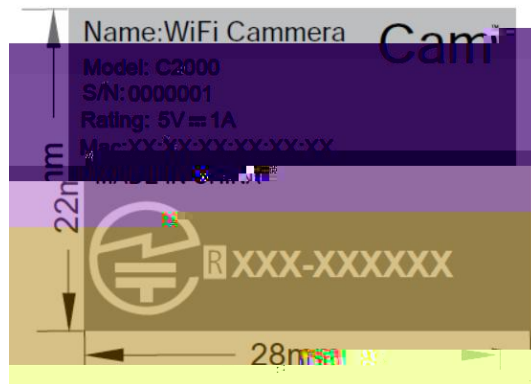
SDoC

Label



# MIC

Label :



A 8F

**IIb**

MDR IIb



EMC 2

- 1 EMC
- 2 EMC

- 1
- 2
- 3 EMC
- 4
- 5

1

- 1
- 2
- 3
- 4

- 1
- 2
- 3
- 4

1

- 1
- 2
- 3
- 4



1  
2  
3  
4  
5

SAR 1

1 SAR SAR  
2 SAR

1  
2 1 RF  
3 CMU200 CMW500  
4

RF 1

1  
2  
3

1  
2 1 RF  
3 Bluetooth\Wi-Fi RF

RF/EMC 2

1  
2 CCC CE FCC  
3  
4

1  
2  
3 OFFICE  
4  
5

2

1  
2  
3

1  
2  
3  
4

2  
/ IT/AV// /

2

1  
2  
1  
2  
3

1

1  
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3  
1  
2  
3  
4

2  
/ IT

7.5 08:30-11:45 13:00-17:15  
9 1

1. — —  
2 — — —  
3 — — —

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◇

ROE P™ De#h