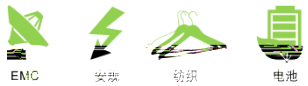
全球认证 本地化服务 Local Service For Global Certification



03 WEEE

04 FCC Supplier ’ s Declaration of Conformity (SDoC)

SDoC 11 2

06 CQC CCC G7(f/ID 68/ang(en-S)>BDC &

WEEE

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2014 2 14 WEEE 2012/19/EU

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2018 8 15 III 6 (ч ص

FCC Supplier ’ s Declaration of Conformity (SDoC)

SDoC 11 2

Mandatory Implementation date

A transition period is provided in the rules allowing use of the former DoC or verification procedures, whichever was previously applicable for a device, until November 2, 2018.

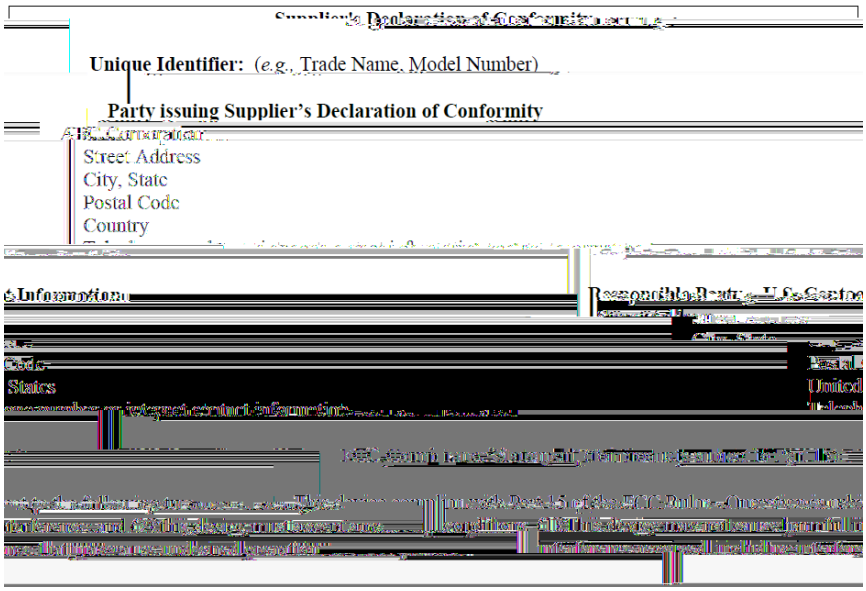
2017 11 2 FCC FCC DoC & Verification SDoC 2018 11 2 FCC SDoC

SDoC

SDoC

- The responsible party, who must be located in the United States (provide their name, address and telephone number or internet contact information) C .
- is not required to file an equipment authorization application with the Commission or a TCB.
  SDoC FCC TCB .
- Equipment authorized under the SDoC procedure is not listed in a Commission database.
  SDoC FCC .
- The responsible party or any other party marketing the equipment must provide a test report and other information demonstrating compliance with the rules upon request by the Commission.
  .
- The responsible party has the option to use the certification procedure in place of the SDoC procedure.
  Certification SDoC .

– **FCC Part15B-**


Unique Identifier: (e.g., Trade Name, Model Number)
Party issuing Supplier's Declaration of Conformity
Street Address
City, State
Postal Code
Country

CQC CCC GB 4343.1-2018

CQC

2018 9 12 2020 6 1

2020 6 1

2018 9 12

CQC

2021 6 1 CQC 2021 9 1

REACH 17

2018 10 12 (EU)2018/1513 REACH (EC)No1907/2006 XVII
(CMR)1A 1B
XVII 72 , XII 2020 11 1

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2. (“ ”
)
3.

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4.
5. (EU) 2016/425
6. (EU) 2017/745

	CAS NO	

XVII 28

	605-50-5	
(DPP)	131-18-0	
(DnHP)	84-75-3	
N- 1- -2- (NMP)	872-50-4	< 3000 mg/kg
N,N- (DMAC)	127-19-5	< 3000 mg/kg
N,N- (DMF)	68-12-2	< 3000 mg/kg
1	2475-45-8	< 50 mg/kg
9	569-61-9	< 50 mg/kg
3 ≥ 0.1 % (EC 202-027-5)	548-62-9	< 50 mg/kg
4- -	3165-93-3	< 30 mg/kg
2-	553-00-4	< 30 mg/kg
2,4-	39156-41-7	< 30 mg/kg
2,4,5-		

FDA

FDA 2018 7 30 2019 (2018 10 1 – 2019 9 30) FDA

	2018	2019
	USD4,624	USD4,884
510K	USD10,542	USD10,953 USD2,738 FDA

*** FDA 1 , 1-2 FDA**

/

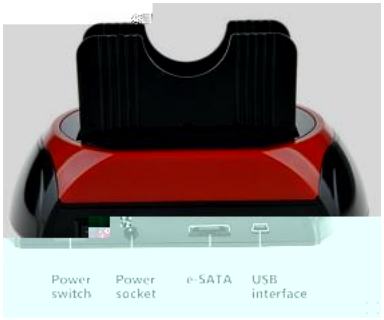
AS/NZS 62368.1

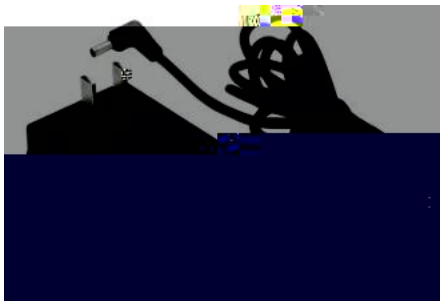
/ IEC62368-1:2014 AU/NZ National difference AS/NZS 62368.1:2018 6.201

Docking Station

1		10		=12Vdc	13.2Vdc	
2	USB	3 V	10		=5Vdc	8Vdc

*





FDA

FDA , ,

1.

, : WIFI , GPRS …

2.

IEEE ANSI C63.27:2017 American National Standard for Evaluation of Wireless Coexistence

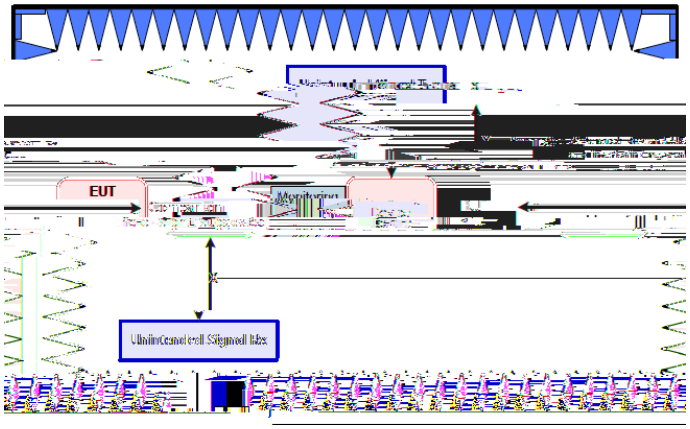
AAMI TIR69:2017 Risk management of radio-frequency wireless coexistence for medical devices and systems

3.

, , :

1	(Throughput)	1.5Mb/s
2	(Latency)	<10 second
3	(Packet Error Rate)	<10%
4	(Availability)	<24hour

:



, , FDA ,

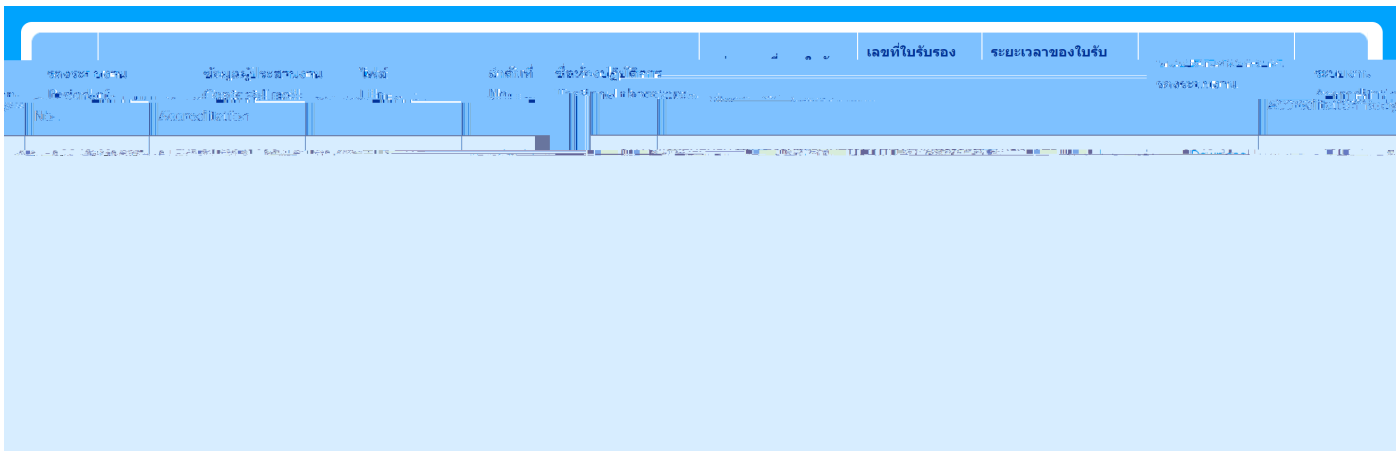
FDA

NBTC

NBTC ” National Broadcasting and Telecommunications Commission ” , , NBTC

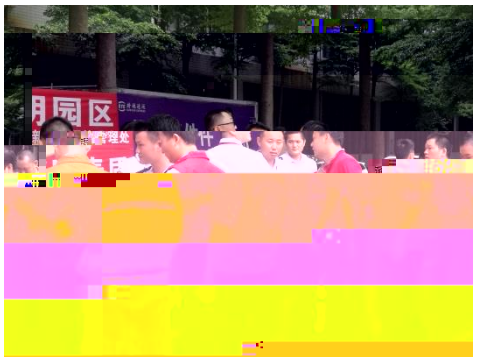
RF( )/Telecom ( )

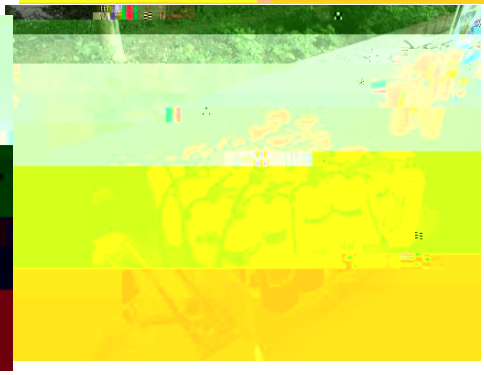
NBTC 2013 7 2024 2 27



NBTC Class A/ Class B SDoC

11 15





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