

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/angen-5)BDC f

WEEE

WEEE

2014 2 14

WEEE 2012/19/EU
WEEE

2018 8 15

III 6

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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) ☐
- 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-

Supplier's Declaration of FCC Compliance	
Unique Identifier: (e.g., Trade Name, Model Number)	
Party issuing Supplier's Declaration of Conformity	
Street Address	
City, State	
Postal Code	
Country	
Party, U.S. Contact Information	Responsible
Postal Code	
United States	
FCC Compliance Statement	

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

- 1.
- 2.
- 3.
- 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

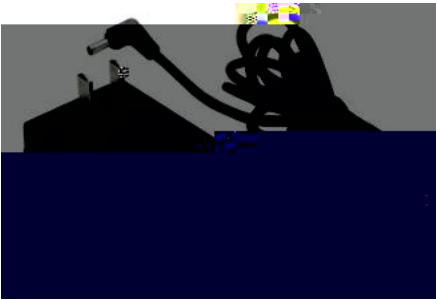
	2018	2019
	USD4,624	USD4,884
510K	USD10,542	USD10,953 USD2,738 FDA

* FDA	1	1-2	FDA
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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 ...

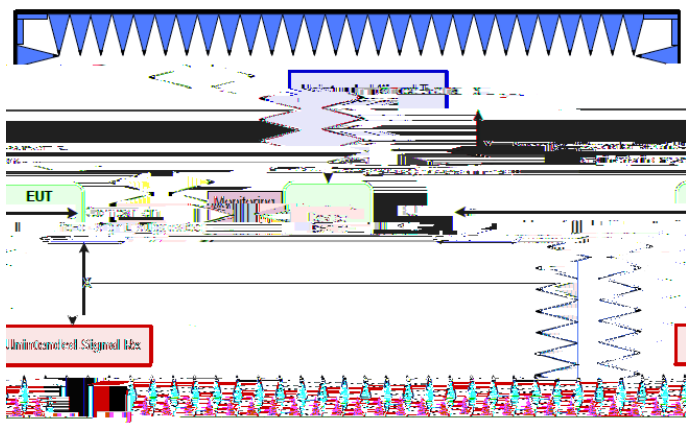
2.

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
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[illegible]

NBTC	Class A/ Class B	SDoC

11 15



