

## Verification Report

No. CANEC2210390701

Date: 10 Jun 2022

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Client Name : Wenatone Medical Technology Co.,Ltd.

Client Address : 8th Floor,Jianye Building,#96 Xiangxing Road,Torch Hi-Tech District,Xiangan,Xiamen

Sample Name : Ear canal hearing aid

Tested Basic Model No. VR-L50-C

(P.O.No) :

The above sample(s) and information were provided by the client.

SGS Job No. : 22660618 - XM

Date of Sample Received : 20 May 2022

Verification Period : 20 May 2022 - 10 Jun 2022

Verification Requested : With reference to RoHS Directive (EU) 2015/863 amending 2011/65/EU.

Verification Method(s) : Please refer to next page(s).

Verification Result(s) : Please refer to next page(s).

Verification Conclusion : Based on the verification results of the submitted samples, the results of Lead, Mercury, Cadmium, Hexavalent chromium, Polybrominated biphenyls (PBBs), Polybrominated diphenyl ethers (PBDEs) and Phthalates such as Bis(2-ethylhexyl) phthalate (DEHP) , Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) , and Diisobutyl phthalate (DIBP) comply with the limits as set by RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU.

Signed for and on behalf of  
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

*Tyler Zhang*

Tyler Zhang  
Approved Signatory

scan to see the report



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# Verification Report

No. CANEC2210390701

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Verification Method(s) :

1. With reference to IEC 62321-2:2021, review was performed for the samples disjointed from the submitted articles.
2. With reference to IEC 62321-1:2013, tests were performed for the samples indicated by the photos in this report
  - (1) With reference to IEC 62321-3-1:2013, screening by EDXRF spectroscopy.
  - (2) Wet chemical test method: With reference to IEC 62321-4:2013+A1:2017, IEC62321-5:2013, IEC 62321-7-1:2015, IEC 62321-7-2:2017, ISO 17075-1:2017, IEC 62321-6:2015 and IEC62321-8:2017, analyzed by ICP-OES,UV-Vis and GC-MS.

In accordance with the result of material risk assessment, the following disjointed parts in the submitted sample have been verified.

Part No.	Part Description	Restricted Substances	Results of EDXRF <sup>(1)</sup>	Screening Result of PHTH <sup>(2)</sup>	Result of Wet Chemical Testing <sup>(3)</sup> (mg/kg)	Conclusion	Sample Submitted / Resubmitted Date
1	Brown plastic shell with black printing	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	BL	---	---	Comply	
		PBDEs	BL	---	---	Comply	
		DBP	---	BL	---	Comply	
		BBP	---	BL	---	Comply	
		DEHP	---	BL	---	Comply	
DIBP	---	BL	---	Comply			
2	Translucent glue	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	BL	---	---	Comply	
		PBDEs	BL	---	---	Comply	
		DBP	---	---	ND	Comply	
		BBP	---	---	ND	Comply	
		DEHP	---	---	ND	Comply	
DIBP	---	---	ND	Comply			



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Part No.	Part Description	Restricted Substances	Results of EDXRF <sup>(1)</sup>	Screening Result of PHTH <sup>(2)</sup>	Result of Wet Chemical Testing <sup>(3)</sup> (mg/kg)	Conclusion	Sample Submitted / Resubmitted Date
3	Beige plastic part	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	BL	---	---	Comply	
		PBDEs	BL	---	---	Comply	
		DBP	---	BL	---	Comply	
		BBP	---	BL	---	Comply	
		DEHP	---	BL	---	Comply	
DIBP	---	BL	---	Comply			
4	Silvery metal	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	IN	---	ND	Comply	
		PBBs	---	---	---	---	
		PBDEs	---	---	---	---	
		DBP	---	---	---	---	
		BBP	---	---	---	---	
		DEHP	---	---	---	---	
DIBP	---	---	---	---			
5	Silvery metal solder	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	---	---	---	---	
		PBDEs	---	---	---	---	
		DBP	---	---	---	---	



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Part No.	Part Description	Restricted Substances	Results of EDXRF <sup>(1)</sup>	Screening Result of PHTH <sup>(2)</sup>	Result of Wet Chemical Testing <sup>(3)</sup> (mg/kg)	Conclusion	Sample Submitted / Resubmitted Date
		BBP DEHP DIBP	--- --- ---	--- --- ---	--- --- ---	--- --- ---	
6	Copper-colored enamel-insulated wire	Pb Cd Hg Cr(VI)▼ PBBs PBDEs DBP BBP DEHP DIBP	BL BL BL BL BL BL --- --- --- ---	--- --- --- --- --- --- BL BL BL BL	--- --- --- --- --- --- --- --- --- ---	Comply Comply Comply Comply Comply Comply Comply Comply Comply Comply	20 May 2022
7	Silvery metal sheet	Pb Cd Hg Cr(VI)▼ PBBs PBDEs DBP BBP DEHP DIBP	BL BL BL BL --- --- --- --- --- ---	--- --- --- --- --- --- --- --- --- ---	--- --- --- --- --- --- --- --- --- ---	Comply Comply Comply Comply --- --- --- --- --- ---	20 May 2022



Part No.	Part Description	Restricted Substances	Results of EDXRF <sup>(1)</sup>	Screening Result of PHTH <sup>(2)</sup>	Result of Wet Chemical Testing <sup>(3)</sup> (mg/kg)	Conclusion	Sample Submitted / Resubmitted Date
8	Silvery metal sheet	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	---	---	---	---	
		PBDEs	---	---	---	---	
		DBP	---	---	---	---	
		BBP	---	---	---	---	
		DEHP	---	---	---	---	
9	Silvery metal part	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	IN	---	ND	Comply	
		PBBs	---	---	---	---	
		PBDEs	---	---	---	---	
		DBP	---	---	---	---	
		BBP	---	---	---	---	
		DEHP	---	---	---	---	
10	Brown plastic part	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	BL	---	---	Comply	
		PBDEs	BL	---	---	Comply	
		DBP	---	BL	---	Comply	



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Part No.	Part Description	Restricted Substances	Results of EDXRF <sup>(1)</sup>	Screening Result of PHTH <sup>(2)</sup>	Result of Wet Chemical Testing <sup>(3)</sup> (mg/kg)	Conclusion	Sample Submitted / Resubmitted Date
		BBP	---	BL	---	Comply	
		DEHP	---	BL	---	Comply	
		DIBP	---	BL	---	Comply	
11	Brown plastic part	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	BL	---	---	Comply	
		PBDEs	BL	---	---	Comply	
		DBP	---	BL	---	Comply	
		BBP	---	BL	---	Comply	
		DEHP	---	BL	---	Comply	
		DIBP	---	BL	---	Comply	
12	Golden metal sheet	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	IN	---	ND	Comply	
		PBBs	---	---	---	---	
		PBDEs	---	---	---	---	
		DBP	---	---	---	---	
		BBP	---	---	---	---	
		DEHP	---	---	---	---	
		DIBP	---	---	---	---	



Part No.	Part Description	Restricted Substances	Results of EDXRF <sup>(1)</sup>	Screening Result of PHTH <sup>(2)</sup>	Result of Wet Chemical Testing <sup>(3)</sup> (mg/kg)	Conclusion	Sample Submitted / Resubmitted Date
13	Silvery metal solder	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	---	---	---	---	
		PBDEs	---	---	---	---	
		DBP	---	---	---	---	
		BBP	---	---	---	---	
		DEHP	---	---	---	---	
		DIBP	---	---	---	---	
14	Brown plastic button	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	BL	---	---	Comply	
		PBDEs	BL	---	---	Comply	
		DBP	---	BL	---	Comply	
		BBP	---	BL	---	Comply	
		DEHP	---	BL	---	Comply	
		DIBP	---	BL	---	Comply	
15	Silvery metal shaft	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	IN	---	ND	Comply	
		PBBs	---	---	---	---	
		PBDEs	---	---	---	---	
		DBP	---	---	---	---	



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Part No.	Part Description	Restricted Substances	Results of EDXRF <sup>(1)</sup>	Screening Result of PHTH <sup>(2)</sup>	Result of Wet Chemical Testing <sup>(3)</sup> (mg/kg)	Conclusion	Sample Submitted / Resubmitted Date
		BBP DEHP DIBP	--- --- ---	--- --- ---	--- --- ---	--- --- ---	
16	Black body	Pb Cd Hg Cr(VI)▼ PBBs PBDEs DBP BBP DEHP DIBP	BL BL BL BL BL BL --- --- --- ---	--- --- --- --- --- --- BL BL BL BL	--- --- --- --- --- --- --- --- --- ---	Comply Comply Comply Comply Comply Comply Comply Comply Comply Comply	20 May 2022
17	Silvery metal wire (solder)	Pb Cd Hg Cr(VI)▼ PBBs PBDEs DBP BBP DEHP DIBP	BL IN BL BL --- --- --- --- --- ---	--- --- --- --- --- --- --- --- --- ---	--- ND --- --- --- --- --- --- --- ---	Comply Comply Comply Comply --- --- --- --- --- ---	20 May 2022 07 Jun 2022





Part No.	Part Description	Restricted Substances	Results of EDXRF <sup>(1)</sup>	Screening Result of PHTH <sup>(2)</sup>	Result of Wet Chemical Testing <sup>(3)</sup> (mg/kg)	Conclusion	Sample Submitted / Resubmitted Date
18	Golden body	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	BL	---	---	Comply	
		PBDEs	BL	---	---	Comply	
		DBP	---	BL	---	Comply	
		BBP	---	BL	---	Comply	
		DEHP	---	BL	---	Comply	
		DIBP	---	BL	---	Comply	
19	Green "PCB"	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	BL	---	---	Comply	
		PBDEs	BL	---	---	Comply	
		DBP	---	---	ND	Comply	
		BBP	---	---	ND	Comply	
		DEHP	---	---	ND	Comply	
		DIBP	---	---	ND	Comply	
20	Silvery metal solder	Pb	BL	---	---	Comply	20 May 2022
		Cd	BL	---	---	Comply	
		Hg	BL	---	---	Comply	
		Cr(VI)▼	BL	---	---	Comply	
		PBBs	---	---	---	---	
		PBDEs	---	---	---	---	
		DBP	---	---	---	---	



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Part No.	Part Description	Restricted Substances	Results of EDXRF <sup>(1)</sup>	Screening Result of PHTH <sup>(2)</sup>	Result of Wet Chemical Testing <sup>(3)</sup> (mg/kg)	Conclusion	Sample Submitted / Resubmitted Date
		BBP DEHP DIBP	--- --- ---	--- --- ---	--- --- ---	--- --- ---	
21	Green "PCB"	Pb Cd Hg Cr(VI)▼ PBBs PBDEs DBP BBP DEHP DIBP	BL BL BL BL IN IN --- --- --- ---	--- --- --- --- --- --- --- --- --- ---	--- --- --- --- ND ND ND ND ND ND	Comply Comply Comply Comply Comply Comply Comply Comply Comply Comply	20 May 2022
22	Silvery metal solder	Pb Cd Hg Cr(VI)▼ PBBs PBDEs DBP BBP DEHP DIBP	BL BL BL BL --- --- --- --- --- ---	--- --- --- --- --- --- --- --- --- ---	--- --- --- --- --- --- --- --- --- ---	Comply Comply Comply Comply --- --- --- --- --- ---	20 May 2022



Remark

(1) Interpretation of screening results by X-ray fluorescence spectrometry (XRF):

(a) Screening limits in mg/kg for regulated elements in various matrices according to IEC 62321-1:2013 Annex A as below table.

Element	Polymer	Metal	Composite Materials
Cd	$BL \leq (70-3\sigma) < X < (130+3\sigma) \leq OL$	$BL \leq (70-3\sigma) < X < (130+3\sigma) \leq OL$	$LOD < X < (150+3\sigma) \leq OL$
Pb	$BL \leq (700-3\sigma) < X < (1300+3\sigma) \leq OL$	$BL \leq (700-3\sigma) < X < (1300+3\sigma) \leq OL$	$BL \leq (500-3\sigma) < X < (1500+3\sigma) \leq OL$
Hg	$BL \leq (700-3\sigma) < X < (1300+3\sigma) \leq OL$	$BL \leq (700-3\sigma) < X < (1300+3\sigma) \leq OL$	$BL \leq (500-3\sigma) < X < (1500+3\sigma) \leq OL$
Br	$BL \leq (300-3\sigma) < X$	Not applicable	$BL \leq (250-3\sigma) < X$
Cr	$BL \leq (700-3\sigma) < X$	$BL \leq (700-3\sigma) < X$	$BL \leq (500-3\sigma) < X$

(b) If the maximum allowed level restricts PBB/PBDE and Cr(VI) rather than Br and Cr, the exceptions are the XRF determinations of Br and Cr. If the quantitative results for the elements Br and /or are higher than the limit (for Br calculated based on the stoichiometry of Br in the most common congeners of PBB/PBDE), the sample is “inconclusive”.

(c) Results are obtained by EDXRF for primary screening, LOD = Limit of Detection, BL = Below Limit, OL = Over Limit, IN (The symbol X marks the region)= Inconclusive, where further investigation is necessary, and further chemical testing by ICP-OES (for Cd, Pb, Hg), UV-Vis (for Cr(VI)) and GC-MS (for PBBs/PBDEs) are recommended to be performed.

(d) The XRF screening test for RoHS elements – The reading may be different to the actual content in the sample be of non-uniformity composition.

(2) Screening results of Phthalates (PHTH) are for primary screening, and further chemical testing by GC-MS (for DBP, BBP, DEHP and DIBP) are recommended to be performed if the concentration exceeds the below warning value (unit: mg/kg).

Compound	Polymer
DBP	$BL \leq 600 < X$
BBP	$BL \leq 600 < X$
DEHP	$BL \leq 600 < X$
DIBP	$BL \leq 600 < X$

(3) Interpretation of results by chemical tests:

(a) mg/kg = 0.0001%, MDL=Method detection Limit, ND = Not Detected (<MDL), --- = Not Applicable, - = Without BOM.



(b) Unit and MDL in wet chemical test

Test Item	Pb	Cd	Hg	DBP	BBP	DEHP	DIBP
Unit	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg	mg/kg
MDL	10	10	10	100	100	100	100

The MDL for single compound of PBBs and PBDEs is 100 mg/kg,  
 MDL of Cr(VI) for polymer, composite and leather sample is 10 mg/kg.  
 MDL of Cr(VI) for metal sample is 0.10µg/cm<sup>2</sup>.

(c) ▽ =Metal sample

- a. The sample is positive for Cr(VI) if the Cr(VI) concentration is greater than 0.13 µg/cm<sup>2</sup>.  
 The sample coating is considered to contain Cr(VI)
- b. The sample is negative for Cr(VI) if Cr(VI) is ND (concentration less than 0.10 µg/cm<sup>2</sup>).  
 The coating is considered a non-Cr(VI) based coating
- c. The result between 0.10 µg/cm<sup>2</sup> and 0.13 µg/cm<sup>2</sup> is considered to be inconclusive  
 - unavoidable coating variations may influence the determination

Information on storage conditions and production date of the tested sample is unavailable and thus Cr(VI) results represent status of the sample at the time of testing.

(4) Restricted substances and maximum concentration values tolerated by weight in homogeneous materials under RoHS Directive: Cd: 0.01%, Pb/Hg/Cr(VI)/PBBs/PBDEs/DEHP/DBP/BBP/DIBP: 0.1%. The limit is quoted from RoHS Directive (EU) 2015/863.

(5) IEC 62321 series is equivalent to EN 62321 series.

[https://www.cenelec.eu/dyn/www/f?p=104:30:1742232870351101:::FSP\\_ORG\\_ID,FSP\\_LANG\\_ID:1258637.2](https://www.cenelec.eu/dyn/www/f?p=104:30:1742232870351101:::FSP_ORG_ID,FSP_LANG_ID:1258637.2)

5

Unless otherwise stated, the decision rule for conformity reporting is based on Binary Statement for Simple Acceptance Rule (w=0) stated in ILAC-G8:09/2019.

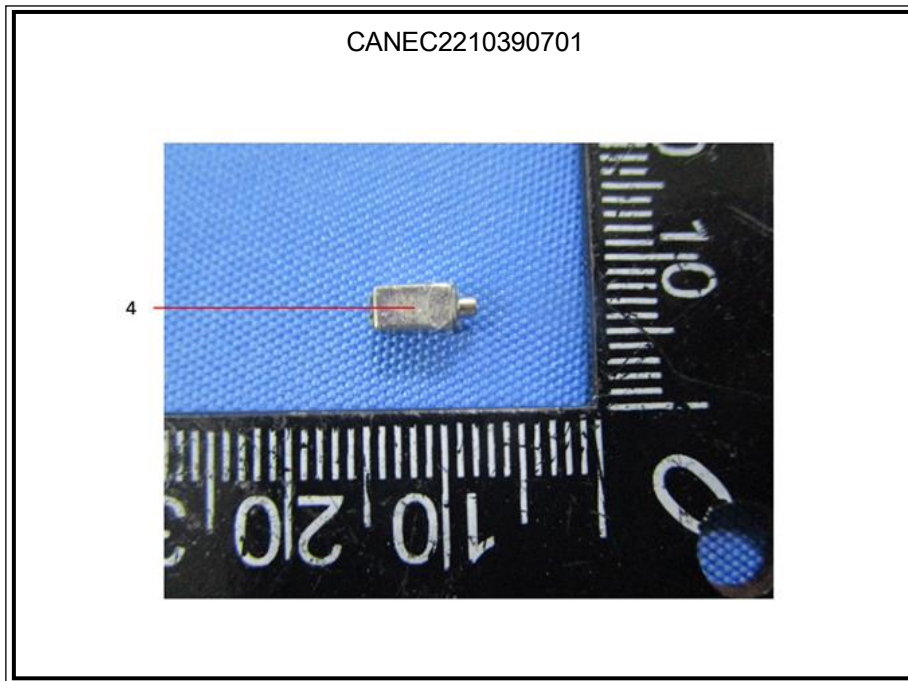
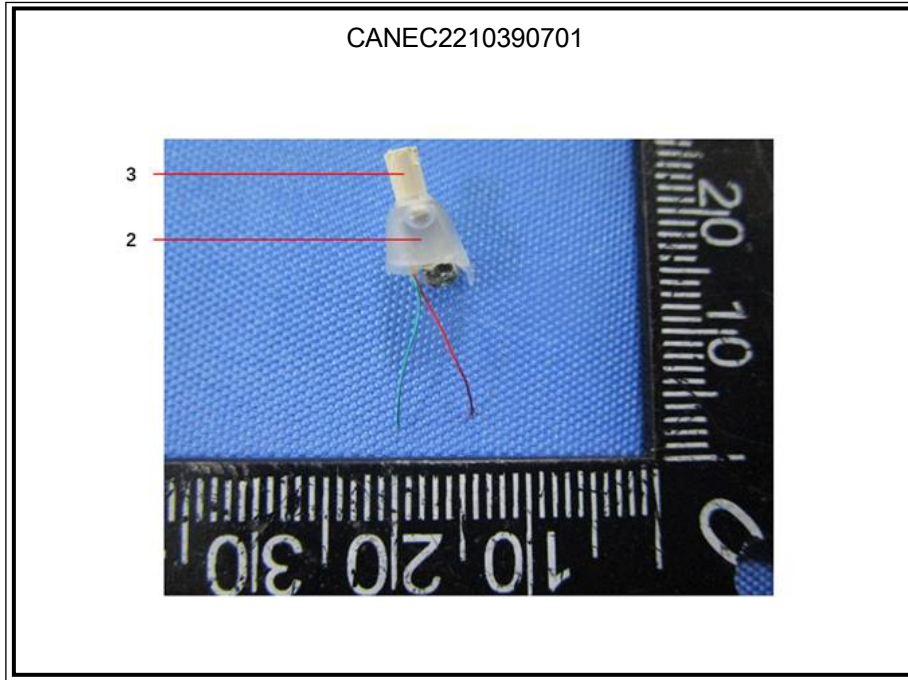


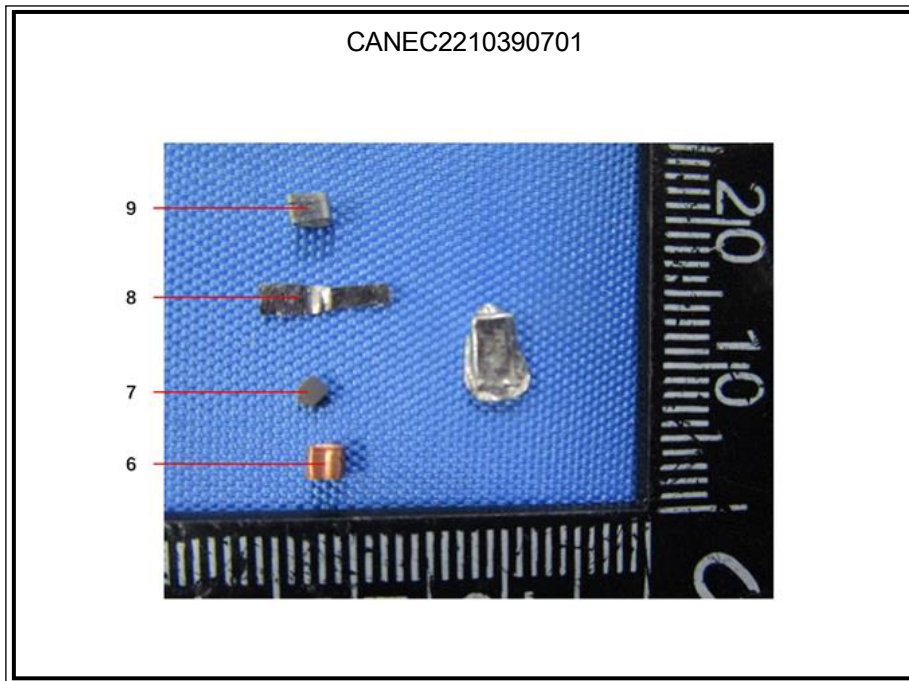
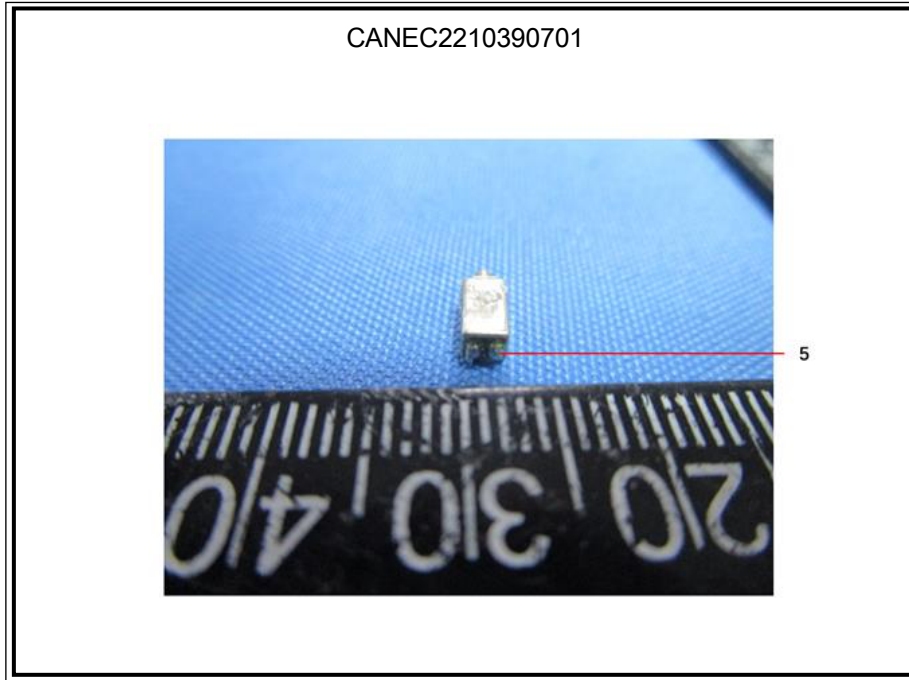


Sample photo:

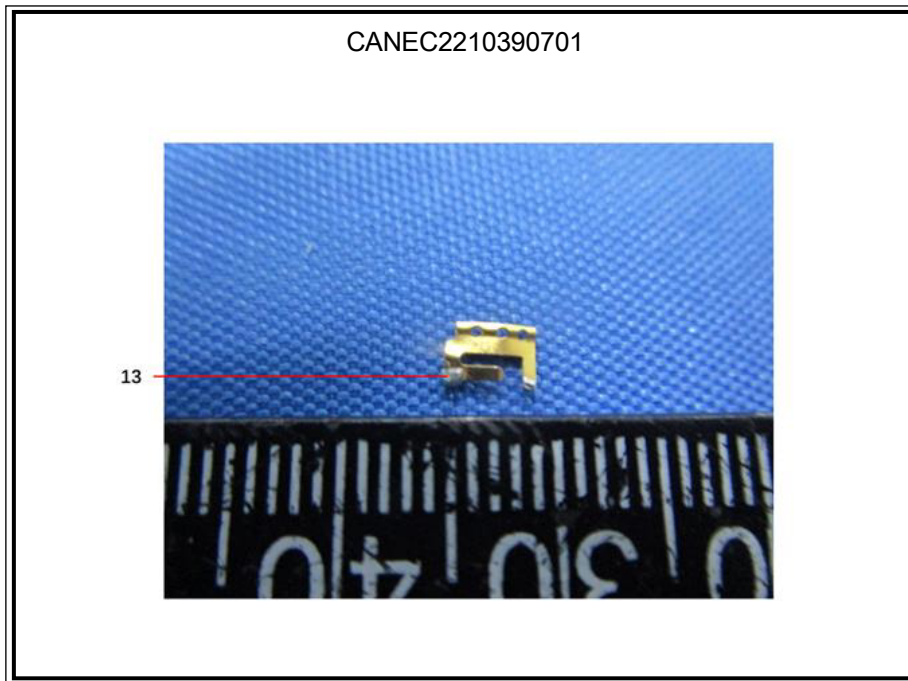
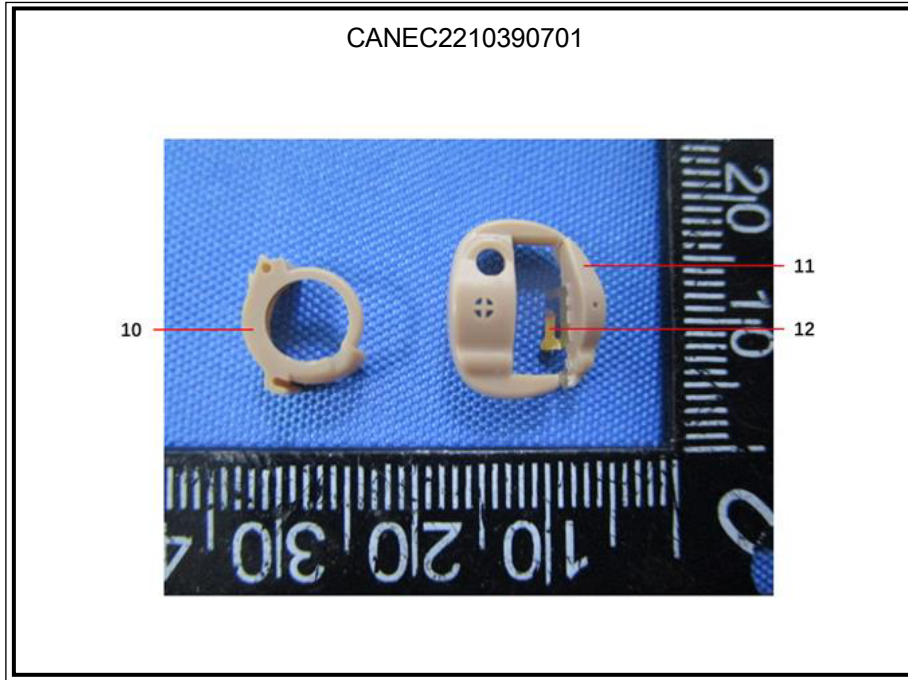


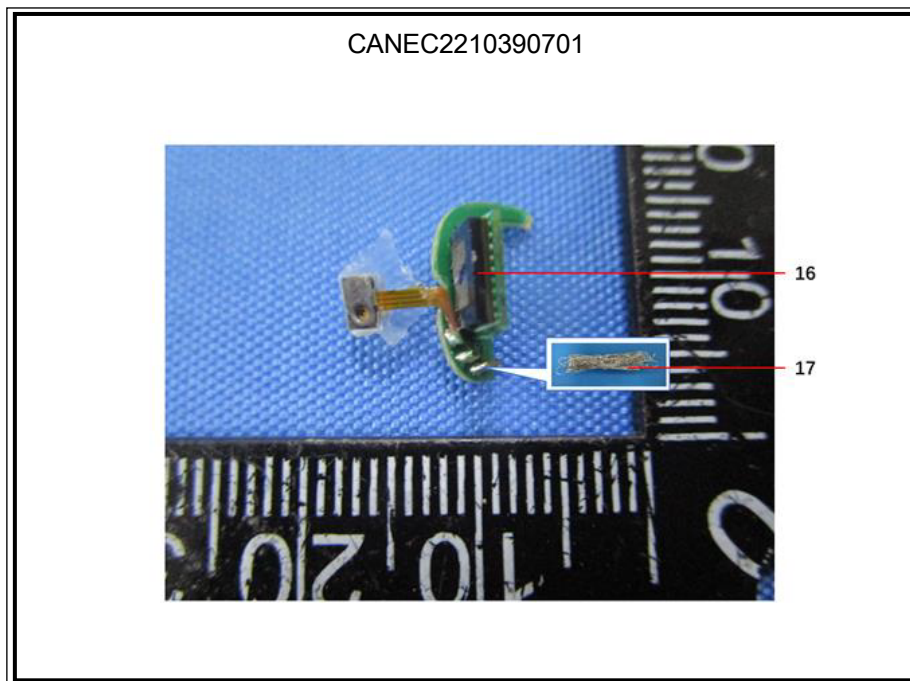
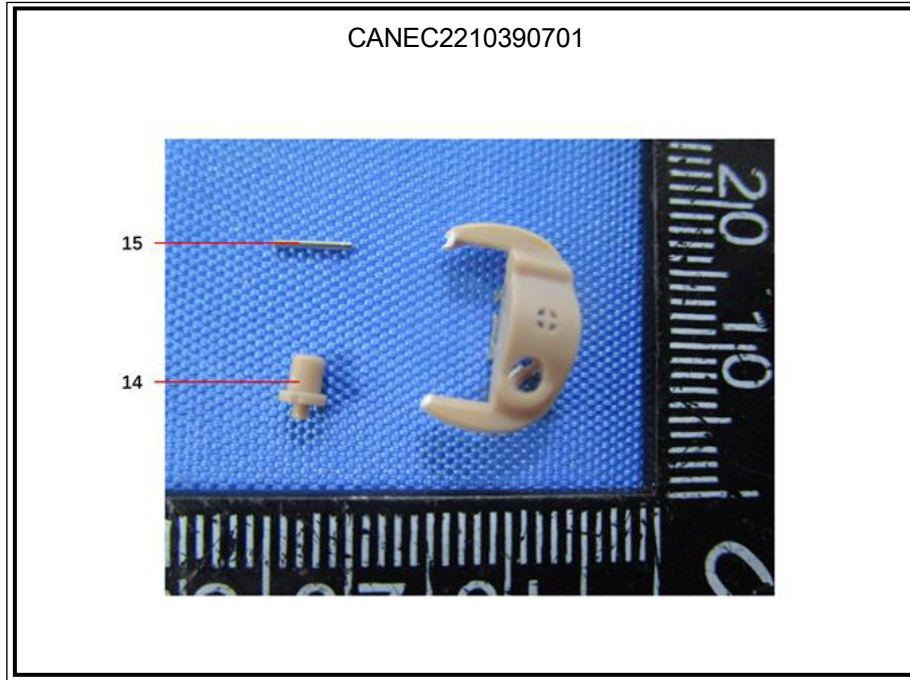




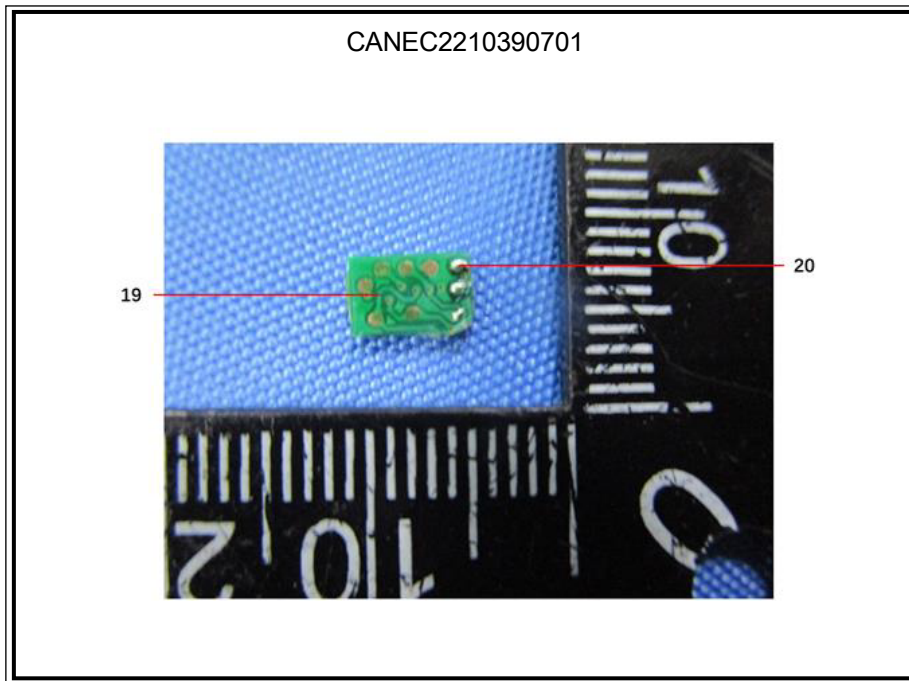
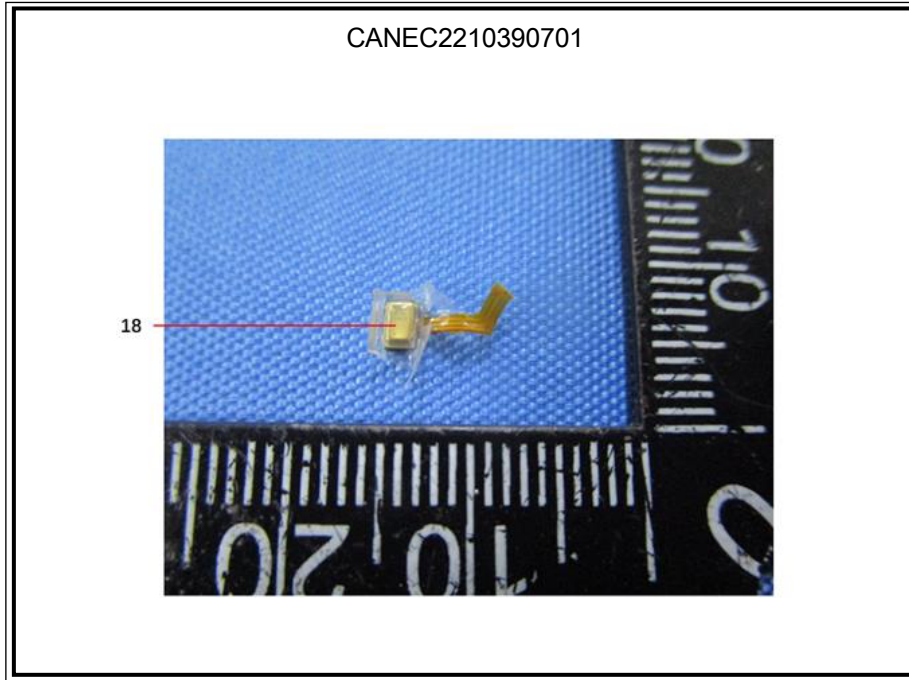




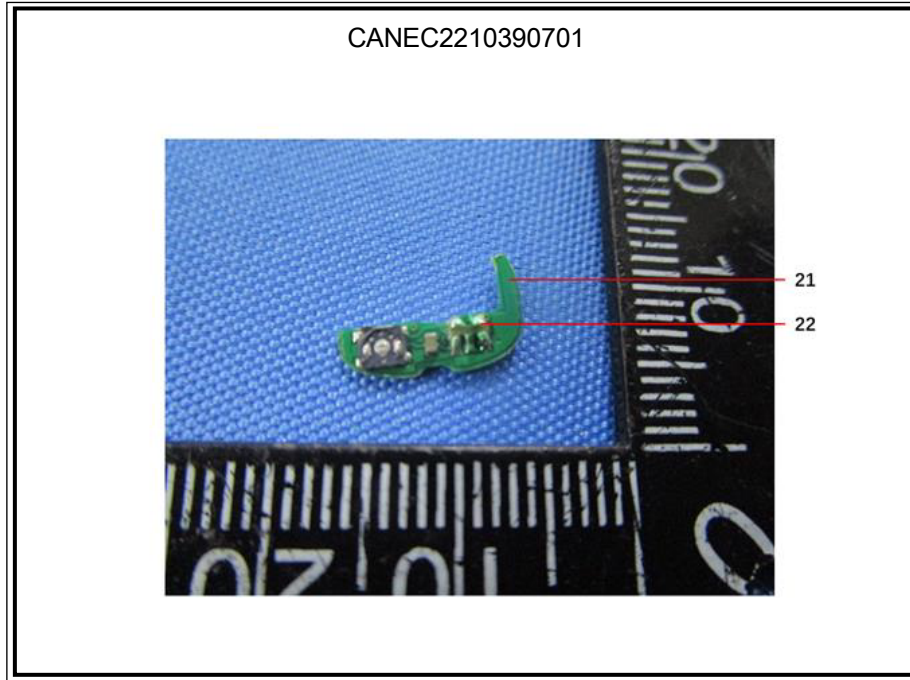












SGS authenticate the photo on original report only

\*\*\* End of Report \*\*\*

