

Test Report

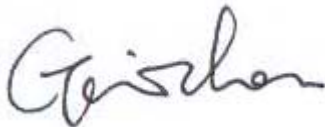
Report No.: GNBZ20090122-01-01EN

Date: 2020-09-29

Page 1 of 8

Applicant : Sailray Medical System Co., Ltd.
Address : Room 1012, Building B, Ruiding Mansion, No.200 Zhenhua Road, Sandun Town, Xihu District, Hangzhou
Sample Name : X-ray hand switch
Tested Model : HS-01
Model/Type reference : HS-01-1, HS-01-2, HS-01-3, HS-02, HS-02-1, HS-02-2, HS-02-3, HS-03, HS-03-1, HS-03-2, HS-03-3, HS-04, HS-04-1, HS-04-2, HS-04-3, HS-05, HS-05-1, HS-06, HS-06-1, HS-06-2, HS-07
Sample Receiving date : 2020-09-01
Test period : 2020-09-01 – 2020-09-29
Test Requirement : The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, RoHS Directive 2011/65/EU and its amendment Directive (EU) 2015/863.
Test Method : Please refer to next page(s).
Test result : Please refer to next page(s).
Conclusion : Based on the verification results of the submitted sample(s), the results of Lead(Pb), Cadmium(Cd), Mercury(Hg), Hexavalent Chromium(CrVI), Polybrominated biphenyls(PBBs), Polybrominated diphenyl ethers(PBDEs), Dibutyl phthalate(DBP), Butyl benzyl phthalate(BBP), Di-2-ethylhexyl phthalate(DEHP) and Di-iso-butyl phthalate(DIBP) content comply with the requirements as set by RoHS Directive 2011/65/EU and its amendment Directive (EU) 2015/863.
Note : The test results are related only to the tested items.

Authorized signature



Lab Manager: Gavin Zhou



2020-09-29

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A. Pb, Cd, Cr(VI), Hg, PBBs&PBDEs**Test Method:**

1. Disassembly, disjointment and mechanical sample preparation
 - Ref. to IEC 62321-2: 2013, Disassembly, disjointment and mechanical sample preparation.
2. With reference to IEC 62321-1: 2013, tests were performed for the samples indicated by the photos in this report.
 - (1) Screening – Lead, mercury, cadmium, total chromium and total bromine
 - Ref. to IEC 62321-3-1: 2013, Screening for Lead, mercury, cadmium, total chromium and total bromine by X-ray fluorescence spectrometry.
 - (2) Wet chemical test method
 - a. Total Lead, Cadmium, Chromium and Mercury content
 - Ref. to IEC 62321-4: 2013, determination of Mercury in polymers, metals and electronics by ICP-OES.
 - Ref. to IEC 62321-5: 2013, determination of Cadmium, lead and chromium in polymers and electronics and cadmium and lead in metals by ICP-OES.
 - b. Chromium (VI) content
 - For Colourless and coloured corrosion-protected coatings on metals, Ref. to IEC 62321-7-1: 2015, determination of presence of hexavalent chromium (Cr(VI)) in colourless and coloured corrosion-protected coatings on metals by the colorimetric method.
 - For polymers and electronics, Ref. to IEC 62321-7-2: 2017, determination of hexavalent chromium (Cr(VI)) in polymers and electronics by the colorimetric method.
 - c. PBBs, PBDEs
 - Ref. to IEC 62321-6: 2015, determination of polybrominated biphenyls and polybrominated diphenyl ethers in polymers by gas chromatography -mass spectrometry (GC-MS).

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Test result(s):

Part No.	Part Description	Results of EDXRF					Chemical confirmation results (mg/kg)	Conclusion
		Pb	Cd	Hg	Cr	Br		
1	White plastic	BL	BL	BL	BL	BL	---	Pass
2	White rubber bushing	BL	BL	BL	BL	BL	---	Pass
3	White plastic	BL	BL	BL	BL	BL	---	Pass
4	White plastic	BL	BL	BL	BL	BL	---	Pass
5	Metal (spring)	BL	BL	BL	IN	---	Cr(VI): Negative	Pass
6	White plastic	BL	BL	BL	BL	BL	---	Pass
7 ^{*1}	Metal (copper nut)	BL	BL	BL	BL	---	---	Pass
8-1	Black plastic shell (switch)	BL	BL	BL	BL	IN	PBBs: N.D. PBDEs: N.D.	Pass
8-2	Gray plastic button	BL	BL	BL	BL	IN	PBBs: N.D. PBDEs: N.D.	Pass
8-3	Black plastic support	BL	BL	BL	BL	BL	---	Pass
8-4	Metal (contact chip)	BL	BL	BL	BL	---	---	Pass
8-5	Metal (pins)	BL	BL	BL	BL	---	---	Pass
9	Soldering tin	110 (BL)	BL	BL	BL	---	---	Pass
10	White plastic casing	BL	BL	BL	BL	BL	---	Pass
11	Heat shrink tubing	BL	BL	BL	BL	BL	---	Pass
12	Copper sheet	BL	BL	BL	BL	---	---	Pass
13	White wire sheath	BL	BL	BL	BL	BL	---	Pass
14	Black wire sheath	BL	BL	BL	BL	BL	---	Pass
15	Green wire sheath	BL	BL	BL	BL	BL	---	Pass
16	Red wire sheath	BL	BL	BL	BL	BL	---	Pass
17	Heat shrink tubing	BL	BL	BL	BL	BL	---	Pass

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Remark:

(^1) “---”= Not Applicable;

(^2) (a) It is the result on total Br while test item on restricted substances is PBBs/PBDEs. It is the result on total Cr while test item on restricted substances is Cr(VI).

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

(c) Results are obtained by EDXRF for primary screening, and further chemical testing by ICP-OES (for Pb、Cd、Hg), UV-VIS (for Cr(VI)) and GC/MSD (for PBBs, PBDEs) is recommended to be performed, if the concentration exceeds the below warning value according to IEC 62321-3-1: 2013.

Attached table 1, XRF screening limits in mg/kg for regulated elements in various matrices:

Element	Polymer Materials	Metallic Materials	Electronics
Cd	$BL \leq (70-3\sigma) < X < (130+3\sigma) \leq OL$	$BL \leq (70-3\sigma) < X < (130+3\sigma) \leq OL$	$LOD < X < (250+3\sigma) \leq OL$
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	$BL \leq (300-3\sigma) < X$	N.A.	$BL \leq (250-3\sigma) < X$
Cr	$BL \leq (700-3\sigma) < X$	$BL \leq (700-3\sigma) < X$	$BL \leq (500-3\sigma) < X$

Note: ① BL “below limit” = the result less than the limit.

② OL “over limit” = the result greater than the limit.

③ IN = inconclusive, the region where need further chemical testing by ICP-OES (for Pb、Cd、Hg), UV-VIS (for Cr(VI)) and GC/MSD (for PBBs, PBDEs).

 ④ 3σ = Repeability of the analyser at the action level.

⑤ LOD = Limit of detection.

(^3) (a) mg/kg=ppm=0.0001%;

(b) N.D. = Not detected (lower than RL);

(c) Reporting Limit (RL) and Limit of Directive 2011/65/EU.

Parameter	Unit	Limit	Reporting Limit (RL)
Lead (Pb)	mg/kg	1000	10
Cadmium (Cd)	mg/kg	100	10
Mercury (Hg)	mg/kg	1000	10
Chromium VI (Cr VI)	mg/kg	1000	R1
Group PBBs	mg/kg	1000	R2
Group PBDEs	mg/kg	1000	R2

 R1: Cr(VI) for metal sample, the reporting limit (RL)= Method Detection Limit (MDL)=0.10 ug/cm².

The reporting limit (RL) of Cr(VI) for polymers and electronics is 10mg/kg.

R2: The reporting limit (RL) for single compound of PBBs & PBDEs is 50mg/kg.

(d) According to IEC 62321-7-1: 2015, result on Cr(VI) for metal sample is shown as Negative, Inconclusive or Positive: Negative = Absence of Cr(VI), Inconclusive = Maybe exist Cr(VI), Positive = Presence of Cr(VI).

Colorimetric result (Cr(VI) concentration)	Qualitative result
The sample solution is < the 0.10 ug/cm ² equivalent comparison standard solution	The sample is negative for Cr(VI)-The Cr(VI) concentration is below the limit of quantification. The coating is considered a non-Cr(VI) based coating.
The sample solution is ≥ the 0.10 ug/cm ² and ≤ the 0.13 ug/cm ² equivalent comparison standard solutions	The result is considered to be inconclusive – Unavoidable coating variations may influence the determination. Recommendation: if addition samples are available, perform a total of 3 trials to increase sampling surface area. Use the averaged result of the 3 trials for the final determination.
The sample solution is > the 0.13 ug/cm ² equivalent comparison standard solution	The sample is positive for Cr(VI)-The Cr(VI) concentration is above the limit of quantification and the statistical margin of error. The sample coating is considered to contain Cr(VI)

(*1) The samples were resubmitted on Sep.28, 2020.

ORIGINAL

Test Report

Report No.: GNBZ20090122-01-01EN

Date: 2020-09-29

Page 6 of 8

B. Phthalates—DBP, BBP, DEHP & DIBP

Test Method: Ref. to IEC 62321-8: 2017

Determination of Phthalates in polymers by Gas Chromatography-Mass Spectrometry (GC-MS)

Test result:

Test item	DBP	BBP	DEHP	DIBP
Maximum Permissible Limit (mg/kg)	1000	1000	1000	1000

Part No.	Test item (mg/kg)				Conclusion
	DBP	BBP	DEHP	DIBP	
1+3+4	N.D.	N.D.	N.D.	N.D.	Pass
2	N.D.	N.D.	N.D.	N.D.	Pass
6	N.D.	N.D.	N.D.	N.D.	Pass
8-1+8-2+8-3	N.D.	N.D.	N.D.	N.D.	Pass
10	270	N.D.	N.D.	N.D.	Pass
11+17	60	N.D.	N.D.	N.D.	Pass
13+14+15	N.D.	N.D.	N.D.	N.D.	Pass
16	N.D.	N.D.	N.D.	N.D.	Pass

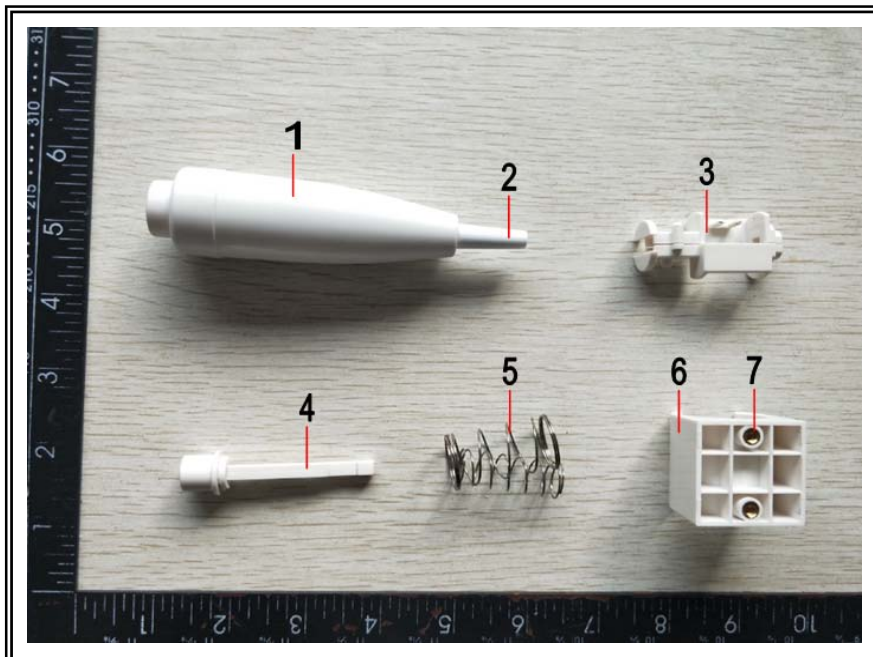
Remark: 1. Reporting Limit (RL) for BBP, DBP, DEHP, DIBP=50mg/kg.
2. N.D. = Not Detected (<RL).

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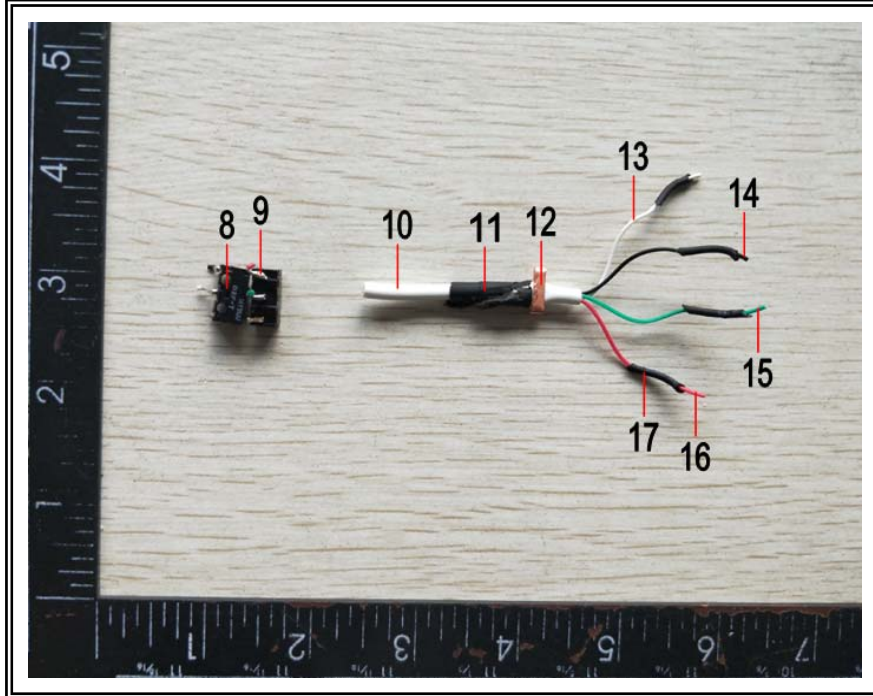
Sample photo(s):



Test item: X-ray hand switch
Tested Model No.: HS-01



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

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