

## Test Report

No. : CM/2013/20182

Date : 2013/03/08

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EVERYWAY MEDICAL INSTRUMENTS CO., LTD.

3FL., NO. 5, LANE 155, SEC. 3, PEISHEN RD., SHENKENG DIST., NEW TAIPEI CITY 222, TAIWAN



**The following samples was/were submitted and identified by/on behalf of the applicant as :**

Applicant : EVERYWAY MEDICAL INSTRUMENTS CO., LTD.  
Sample Description : STAINLESS STEEL PART OF INCONTINENCE ELECTRODE PROBE  
Sample Receiving Date : 2013/02/25  
Testing Period : 2013/02/25 TO 2013/03/08

=====  
**Test Requested** : Nickel Release Test was assigned by the customer to conduct test in accordance with Annex 17 of REACH Regulation (EC) No 1907/2006.

**Test Method** : Please refer to next page(s).

**Test Result(s)** : Please refer to next page(s).

  
  
**James Lu / Supervisor**  
**Signed for and on behalf of**  
**SGS TAIWAN LTD.**  
**Chemical Laboratory – Taipei**

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## Test Result(s)

Sample list/list of materials of Sample :

Sample No.	TEST PART DESCRIPTION
1	SILVER COLORED METAL

**Nickel Release Test (Test Method: With reference to EN 1811:2011+AC:2012. Analysis was performed by ICP-**

Sample	Sample Area (cm <sup>2</sup> )	Volume of Test Solution (ml)	Nickel Release (µg/cm <sup>2</sup> /week)	Specified Limit (µg/cm <sup>2</sup> /week)	Conclusion
1	8.60	10	<0.1	0.5	PASS
			<0.1		
			<0.1		

**Note :** Conclusions on Pass/Fail are based on the test result from the actual sampling of the received samples(s).

- < = less than
- µg/cm<sup>2</sup>/week = microgram per square centimeter per week
- Method Detection Limit = 0.1 µg/cm<sup>2</sup>/week

Type of sample	Nickel Release (µg/cm <sup>2</sup> /week)		
	PASS	No clear decision*	FAIL
Article with Nickel release limit of 0.5µg/cm <sup>2</sup> /week (Non-body piercing)	≤ 0.28	>0.28 and <0.88	≥ 0.88
Article with Nickel release limit of 0.2µg/cm <sup>2</sup> /week (Body piercing)	≤ 0.11	>0.11 and <0.35	≥ 0.35

\* = No clear decision = Inconclusive

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\* The tested sample / part is marked by an arrow if it's shown on the photo. \*

## CM/2013/20182



\*\* End of Report \*\*

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