



AB-0690-T

TR1965391

8-21

TEST REPORT

Job No./Report No TR1965391

Date: 13 August 2021

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The following sample(s) was (were) submitted and identified by/on behalf of the client as:

Sample No.	Sample Description
A	Ti-6Al-4V ELI (TITANIUM F136)

Client's reference No. : TR 1965391
Country of Destination : POLAND
Sample Receiving Date : 19 July 2021
Test Performing Period : 19 July 2021~13 August 2021
Overall Conclusion : **PASS**

Test Results : Please refer to the next page(s).
Performed Test Summary: Selected test(s) as requested by client against Client's performance standard.

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SGS applied shared risk decision rule.

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Test Parameters	Result
Chemical tests	A1
Nickel Release from Coated Samples	M

Remarks	M = Meets client's requirement
	F = Does not meet client's requirement
	I = Inconclusive
	* = No specified requirement
Notes:	Conclusions on meet/fail are based on the test result from the actual sampling of the received sample(s).
	Residual sample can be returned to client if requested.

The test results relate to the tested items only.
Test reports without SGS seal and authorised signatures are invalid.

Issued in Istanbul
Signed for and on behalf of
SGS Supervise Gözetme Etüd Kontrol Servisleri A.Ş.

Mert Kurtuluş
Customer Services Supervisor

Bora Şirinbilek
Hardline & CPCH Testing Services Manager



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Component List / List of Materials for Chemical Test

Sample No.	Sample Description	Material No.	Component	Material	Colour
A	Ti-6Al-4VELI (TITANIUM F136)	A1	Pin	Metal	Silver



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Nickel Release from Coated Samples ¹

Test Method: Simulation of wear and corrosion with reference to EN 12472:2020, followed by extraction with reference to EN 1811:2011 + A1:2015 - Analysis by ICP-MS/ICP-OES

A1

Sample Area (cm²) 1.57

Volume of Test Solution (mL) 1.57

Nickel Release– Trial 1 n.d.

Nickel Release– Trial 2 n.d.

Nickel Release– Trial 3 n.d.

Conclusion Pass

Note(s):

n.d. = not detected

Negative finding by Nickel spot test is observed based on CR 12471:2002 Clause 5.3.4. Simulation of wear and corrosion according to EN 12472:2005+A1:2009 has been applied prior to the EN 1811:2011+A1:2015.

Detection Limit = 0.1 µg/cm²/week

Recommend Max. Limit = Non-body piercing article: 0,5 µg/cm²/week

Body piercing article: 0,2 µg/cm²/week

Remark= Limit specified by entry 27 of Regulation (EC) No 552/2009 amending Annex XVII of REACH Regulation (EC) No 1907/2006 (previously restricted under Directive 94/27/EC and 2004/96/EC).

According to the Commission Communication 2016/C 014/04, published in the OJEU, the EN 1811:2011+A1:2015 is adopted as the harmonized standards under entry 27 of Annex XVII to REACH starting from 15 January 2016.

Comments are given according to Annex A of EN 1811:2011+ A1: 2015 as below:

Type of sample	Nickel Release (µg/cm ² /week)	
	PASS	FAIL
Article with Nickel release limit of 0,5 µg/cm ² /week	< 0,88	≥ 0,88
Article with Nickel release limit of 0,2 µg/cm ² /week	< 0,35	≥ 0,35

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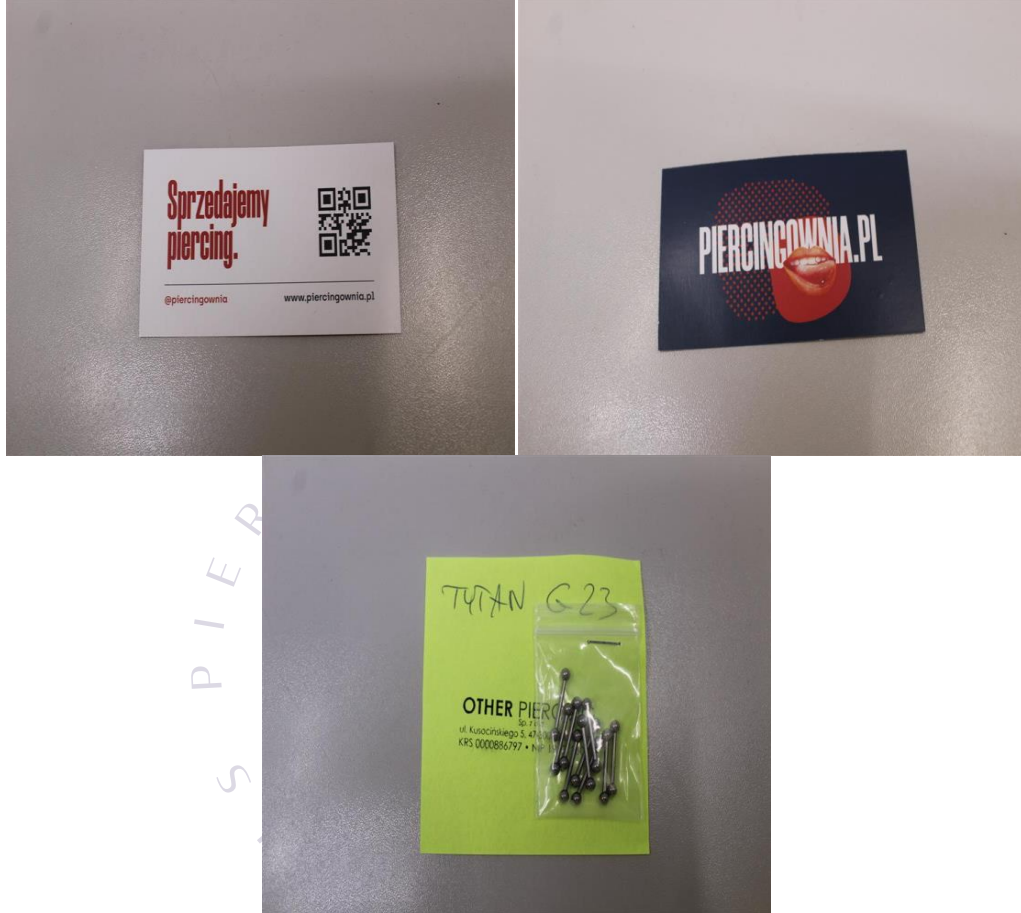
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* * * End of Test Report * * *

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