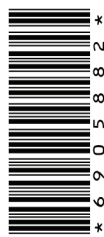


The following sample(s) was (were) submitted and identified by the client as:

Original Sample ID	Sample Description	Sample Receipt Date
240454601	MEDICAL EAR STUDS SUS316L MEDICAL GRADE STAINLESS STEEL	08/05/2024



SGS Customer No : 10190077
SGS Order No : 6997412
Buyer : -
Order No. : - dt. 06/05/2024
Country of Origin : -

Test Performing Period : 22/05/2024 – 03/06/2024
Test Performed : Selected test(s) as requested by applicant

Overall Conclusion : PASS

Test Results : Please refer to the next pages

SGS INSTITUT FRESENIUS GmbH

This test report was electronically created and released:

	date	name	function	department
created	04.06.2024	i.A. Sabrina Schauß	Project Assistant	Connectivity & Products
released	04.06.2024	i.V. Catherine Bouleau	Group Leader Administration Softlines	Connectivity & Products

Test report no. 6905882

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Date: 04.06.2024

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Performed Test Summary:

Test	Result
Nickel Release	M
Nickel Release (coated items)	M
Total Lead Content	M
Total Cadmium Content	M

Remarks:

- M = Meets Client's requirement
- F = Does not meet Client's requirement
- I = Inconclusive
- = No specified requirement

Note: Conclusions on pass/fail are based on the test result from the actual sampling of the received sample(s).

Conclusions are based on the relevant requirements; measurement uncertainties are not taken into account. Only results above the relevant detection limit are taken into account for the calculation of sums.

Test was conducted on composite of random parts of the item as per client's request and the test result is the overall result.

The composite sampling method is based on the client's special request and is a modification from the testing standard.

For 2-composite mix with results exceeding one half of the relevant requirements or 3-composite mix with results exceeding one third of the relevant requirements, the composite sample may have the possibility of one or more components that can lead to a failure result, it is recommended to test on individual basis.

Component List

Component No	Component-ID	Description	Color(s)	Material	Original Sample ID
1	240493858	Earring Stud - whole sample	golden	metal coated	240454601
2	240493859	Earring Stud - head part	golden	metal coated	240454601
3	240493860	Earring Stud - pink part only	golden	metal coated	240454601

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Analytical results

Nickel Release

Test Method

EN 1811 + A1 2015-10 ,with use of ICP-OES, test was conducted in single trial

Sample(s) /Subsample(s)

Result

3

Area

0.4 cm²

Volume of Test Solution

3.0 ml

Nickel Release

< 0.10

Conclusion

Pass

Note:

Unit = µg/cm²/week

Requirement:

Non-body piercing article: <0.5µg/cm²/week

Body piercing article: <0.2 µg/cm²/week

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 harmonised 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:

Article with Nickel release limit of 0.5µg/cm²/week:

Pass: <0.88µg/cm²/week

Fail: > or =0.88µg/cm²/week

Article with Nickel release limit of 0.2µg/cm²/week:

Pass: <0.35µg/cm²/week

Fail: > or =0.35µg/cm²/week

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Nickel Release (coated items)

Test Method

EN 12472:2020, EN 1811:2011+A1:2015, Simulation of wear and corrosion, with use of ICP-OES

Sample(s) /Subsample(s)

Result

2

Area	0.3 cm ²
Volume of Test Solution	3.0 ml
Nickel Release	< 0.10
Conclusion	Pass

Note:

Unit = µg/cm²/week

Requirement:

Non-body piercing article: <0.5µg/cm²/week

Body piercing article: <0.2 µg/cm²/week

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 harmonised 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:

Article with Nickel release limit of 0.5µg/cm²/week:

Pass: <0.88µg/cm²/week

Fail: > or =0.88µg/cm²/week

Article with Nickel release limit of 0.2µg/cm²/week:

Pass: <0.35µg/cm²/week

Fail: > or =0.35µg/cm²/week

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Total Lead Content

Test Method

SOP M 1631 2011-09, analysis was conducted with ICP-OES after digestion

Sample(s) /Subsample(s)

Result

1

Lead (Pb)

< 25 ^[1]

Conclusion

Pass

Note:

Unit = mg/kg

Requirement: < 500 mg/kg (Limit for metal according to Entry 63 Annex XVII of the REACH Regulation No. 1907/2006 and all amendments)

^[1]deviated detection limit

Total Cadmium Content

Test Method

SOP M 1631 2011-09, analysis was conducted with ICP-OES after digestion

Sample(s) /Subsample(s)

Result

1

Cadmium (Cd)

< 2.0 ^[1]

Conclusion

Pass

Note:

Unit = mg/kg

Requirement: < 100 mg/kg (Limit according to Entry 23 Annex XVII of the REACH Regulation No. 1907/2006 and all amendments)

^[1] deviated detection limit

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Attachment: Picture of sample



*** End of test report ***

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