

TEST REPORT

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The results relate only to the item tested.

Report no.: BKKH25002415

Applicant: BODYSTEEL AND SILVER CO., LTD
63 MOO 5, SOI WATBANGCO YAEKRONGFOAM, KANCHANAPHISEK
ROAD., BANGMAENANG, BANGYAI, NONTHABURI 11140
ATTN: K. WALAIRAT

Issued Date: Mar 03, 2025

Sample Submitted:

Quantity of sample:	One (1) bag
Sample description:	Titanium threadless ball
Date sample received:	February 20, 2025

Client Information:

Sample Name:	PVD Product CC-TYBALL 0.5TLx4.0
Sample Description:	CoCr PVD Titanium threadless ball attachment
Item no.:	PVD CoCr coating
Supplier name:	BODYSTEEL AND SILVER CO., LTD
Country of Origin:	Thailand



To be continued

For and on behalf of :
Intertek Testing Services (Thailand) Ltd.,
Hardlines Laboratory

Ladtaka W.

Ladtaka Wongwiboonporn
Operation Manager
Hardlines Department

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Test conducted:

As requested by the applicant, for details please refer to attached page(s)

Conclusion:

<u>Tested samples</u>	<u>Regulation</u>	<u>Result</u>
Submitted sample	Lead content requirement in Regulation (EU) No 836/2012 of the REACH Regulation (EC) No 1907/2006 Annex XVII Item 63	Pass
	Cadmium content requirement in Regulation (EU) No 494/2011 of the REACH Regulation (EC) No 1907/2006 Annex XVII Item 23	Pass
	Nickel release content requirement in Annex XVII Item 27 of the REACH Regulation (EC) No.1907/2006 & Amendment No.552/2009 (Formerly known as Directive 94/27/EC and 2004/96/EC)	Pass



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Test conducted:

1 Total Lead (Pb) Content▲

As per Lead content requirement in Regulation (EU) No 836/2012 of the REACH Regulation (EC) No 1907/2006 Annex XVII Item 63, acid digestion method was used and total Lead content was determined by Inductively Couple Plasma Optical Emission Spectrometry.

<u>Tested samples</u>	<u>Result (%)</u>	<u>LOD (%)</u>	<u>LOQ (%)</u>	<u>Limit (%)</u>
Submitted sample	ND	0.0002	0.0013	0.05

Remark: % = Percentage based on weight of sample;
ND = Not detected (Less than LOD)
LOD = Limit of detection
LOQ = Limit of quantitation
▲ = Tested items are not included in the TISI Accreditation

Tested component: Titanium threadless ball (Body + Pin)

Testing period: February 20, 2025 to February 26, 2025

2 Total Cadmium (Cd) Content▲

As per Cadmium content requirement in Regulation (EU) No 494/2011 of the REACH Regulation (EC) No 1907/2006 Annex XVII Item 23, acid digestion method was used and total Cadmium content was determined by Inductively Couple Plasma Optical Emission Spectrometry.

<u>Tested samples</u>	<u>Result (%)</u>	<u>LOD (%)</u>	<u>LOQ (%)</u>	<u>Limit (%)</u>
Submitted sample	ND	0.0001	0.0005	0.01

Remark: % = Percentage based on weight of sample;
ND = Not detected (Less than LOD)
LOD = Limit of detection
LOQ = Limit of quantitation
▲ = Tested items are not included in the TISI Accreditation

Tested component: Titanium threadless ball (Body + Pin)

Testing period: February 20, 2025 to February 26, 2025

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Test conducted:

- 3 Release of Nickel for Direct Prolonged Skin Contact Item
As per BS EN1811: 2023.

Tested component	Trial	Sample area (cm ²)	Volume of Test solution (ml)	LOD (µg.cm ⁻² .week ⁻¹)	LOQ (µg.cm ⁻² .week ⁻¹)	Result Δ (µg.cm ⁻² .week ⁻¹)
Submitted sample	1	1.90	1.90	0.02	0.10	ND
	2	1.90	1.90	0.02	0.10	ND
	3	1.90	1.90	0.02	0.10	ND

Remark :
 ND = Not detected (Less than LOD)
 LOD = Limit of detection
 LOQ = Limit of quantitation
 µg = Microgram
 cm⁻² = Square centimeter

Requirement: 0.2 µg.cm⁻².week⁻¹

Remark: The limit 0.2mg/cm²/week is applied to post assembly which is the part of the product designed for insertion into the wound caused by piercing, plus any faces that hold the piece in and against the wound

Δ = According to BS EN1811: 2023, EN1811: 2023 (E), compliance decision was made based on the following rules.

Result	Interpretation
< 0.35 µg.cm ⁻² .week ⁻¹	Compliance (Pass)
≥ 0.35 µg.cm ⁻² .week ⁻¹	Non-compliance (Fail)

Tested component: Titanium threadless ball (Body + Pin)

Testing period: February 20, 2025 to March 03, 2025

***** E N D *****/WB/NK

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