

108 – Metal Detectable 4 in 1 Pen

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Declaration of Compliance Statement - 108 - 4 in 1 Pen

Product Code	Description	Ink Colours
108-A05	4 Ink in 1 Pen Retractable	Blue, Black, Green and Red

Regulations and Standards

We confirm that the above mentioned products are suitable for use in contact with all food types and are in conformity with the applicable requirements of the following regulations and standards:

- Regulation (EC) no.1935/2004 on Materials and Articles intended to come into contact with food.
- Commission Regulation (EU) No.10/2011 on Plastic materials intended to come into contact with food including its updates Regulation 1282/2011 and Regulation 1183/2012.
- Regulation (EC) no. 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food.
- Council of Europe Resolution AP 89/1 on the use of Colorants in Plastic Materials coming into contact with food.
- US FDA 21 CFR 177.1520 (Olefin polymers) with colorants and additives cleared for use through listing in 178.3297 (Colorants for polymers), 178.2010 (antioxidants and/or stabilisers for polymers, or other respective parts of the FDA regulations).

Migration test data obtained under short-term repeat use test conditions (6dm²/kg food) has demonstrated that levels of overall migration and specific migration of additives from these products will not exceed the legal limits with all food types.

Test Simulants	Food Types	Testing Condition
A-C, D1, D2 of Regulation No. 10,2011 for Plastic Materials and Articles in contact with food.	All dry, aqueous, acidic, alcoholic and fatty foods.	2 hours at 70C, Repeat use. Test OM3 of regulation 10/2011

Dual-use food additives may be present but any migration into food will be minimal.

This compliance statement is based on information supplied by the polymer and pigment manufacturers, migration testing according to Regulation 10/2011, migration modelling and quality control systems in place at Detectamet.

Supporting documents are available and can be disclosed to the competent authority on request.

REACH - No substances of very high concern (SVHC) above the 0.1% weight (w/w) threshold limit are present in the materials.

Check List	Duration	Tools of Checking	Parameters
Physical Parameters of the component	At the start of the Machine (10 pcs from lot size 50,000)	Digital Caliper / Micrometer	Tube Length - 80.6030.10mm O.D.-2.7530.05mm I.D.-1.65mm Material - PP (H030SG) Tips:- B/P 0.70 BNP 10.50 -60 Needle Length-10.50 mm. Shank Length - 2.50 mm. Shank dia - 1.85 mm. Ball dia - 0.70 mm. Ball Material - Stainless Steel Body Material - Brass Nickel Plating
Tip gap / Adaptor gap	Every two hours	Visual	Must be nil
Ink Level	Every two hours	Digital Caliper	From apex part of tip (69.033.5)mm
Ink Qty	During setting time	Weighing Scale	0.17 gm/pc
Grease Level	N.A.	N.A.	N.A.
Grease Qty	N.A.	N.A.	N.A.
Stress mark on backside of imprint	During setting time	Visual	Must be nil
Writing Length		Write Test M/C	950-1050mtrs.
Ink lay down		Write Test M/C	15320% mg/100mtrs
Shelf life		Humidifier Oven, Ambient condition	2 years
Rubber Seal		N.A.	N.A.

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