


## Declaration of compliance statement

Products not used in direct contact with food: Pens

### 1.- PRODUCT IDENTIFICATION

#### Detectable product – Pen

Product code	Product name	Photo	Temperature range (°C)	Housing Colour	Ink Colour
DP0009-	Metal Detectable & X Ray Detectable retractable pen with clip		From 0 to 45	2	2 3 6
DP0007	Metal Detectable & X Ray Detectable retractable pen with clip		From -10 to +80	2	2
DP0012	Metal Detectable & X Ray Detectable retractable pen with clip		From -30 to +120	2	2

**Materials used** in the manufacture of these products are in conformity with the applicable requirements of the following regulations and standards:

**Acetal resin** – in which the basic polymer chemically consists of a polyoxymethylene, has the following status relative to food contact regulations in Europe.

We can confirm that the product plastic accordance with the Regulation (EC) No. 1935/2004 in term of specific measures for groups of materials – in case, plastics – in from of Regulation (EU) No. 10/2011 incl. amendments, the enclosed declaration of conformity and by having installed a traceability system. Furthermore, the product is in accordance with the Regulation (EC) No. 2023/2006 (Article 5, 6, und 7). The components and monomers of the product are listed in the Regulations (EU) No. 10/2011 and amendments.

The specific migration limits applies as follows:

#### Migration Limits:

- Formaldehyde (CAS 50-00-0): SML(T) = 15 mg/kg food
- 1,3-dioxolane (CAS 646-06-0): SML = 5 mg/kg food
- 1,3,5-trioxane (CAS 110-88-3): SML = 5 mg/kg food
- Triethyleneglycol-bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate] (CAS 36443-68-2): SML = 3 mg/kg food
- Melamine (CAS 108-78-1): SML = 2.5 mg/kg food



Statement of a raw material supplier for one component: ...Listed (10/2011/EC) Iron Oxide has CAS 1332-37-2. This Iron Oxide has a molecular formula unspecified and hence includes any generic Iron Oxide material... Therefore the used component can safely be added in plastics without restriction.

The product does not contain any dual-use additives.

The colorants fulfil the requirements of the European Resolution AP(89)1.

#### USA:

The components are listed e.g. FDA under 21 CFR §§ 177.2470, 178.2010, 178.3297, 186.1374 (GRAS)

The following restrictions apply for one component:

- Types of food except foods containing 15% or more alcohol.
- Conditions of use: Use temperature shall not exceed 120°C [per CFR177.2470]
- Application: Repeated use articles only per 21CFR177.2470

**The suitability of the finished article for the intended use (food contact) must be checked by the manufacturer or seller.**

Declaration on behalf of DETECTA PLASTICS, S.L.

Vilassar de Mar, January 8<sup>th</sup>, 2018.

**DETECTA-PLASTICS, S.L.**

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We do not accept liability for loss or damage arising from the use of this information.

Results are based on a test sample, our general experience and information from our suppliers.

Data and results must be confirmed by the buyer by testing for its intended conditions of use.