

Declaration of Compliance Statement

Retractable Cryo Pens - metal detectable; blue housing with red cap	Pressure refill + clip	Blue ink	DTMCR 0027
	Pressure refill + lanyard attachment	Blue ink	DTMCR 0027 LY
Retractable Cryo Pens - metal detectable and X-ray visible, blue housing	c/w pressure refill + clip	Blue ink	DTMXD 0070

Materials used in the manufacture of these products 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 on the materials used 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 70°C, repeat use. Test OM3 of Regulation 10/2011

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

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

This Declaration of Compliance Statement is for the products specified above and is based on information supplied by our supplier. An updated statement will be provided if the information on which the declaration is based changes or regulatory requirements impact on its validity.

Kind regards


Jan Skov Trabjerg
Technical Manager
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