

Declaration of Compliance for articles intended for food contact

Watson-Marlow confirms that PureWeld XL, thermoplastic elastomer tubing, PureWeld XL Loadsure elements and Pureweld XL Y-elements, comply with the legal regulations laid down in the Regulation (EC) No. 1935/2004. This includes manufacture according to GMP principles, compliant with (EC) No 2023/2006.

PureWeld XL also meets the requirements of the associated legislation for plastics in contact with food – EU 10/2011. When used as specified, the overall migration levels as well as the specific migration levels do not exceed the legal limits. The testing was performed according to EU 10/2011.

The materials and raw materials used in the manufacture of PureWeld XL comply with EU 10/2011. There are three restricted proprietary substances with migration restrictions;

- 1-Octene
- Octadecyl 3-(3,5-di-tert-butyl-4hydroxyphenyl)propionate
- Didodecyl 3,3'-thiodipropionate

Compliance has been confirmed by independent testing.

There are two dual use additives;

- Glyceryl Monostearate
- Amorphous Silica

The overall migration levels and the specific migration levels of the PVDF connectors used in Loadsure and Y-elements do not exceed the legal limits defined in EU10/2011. The connectors contain one restricted proprietary substance with migration restrictions; Vinylidene Fluoride.

Specification of the intended use or restrictions:

- Types of food intended to come into repeated contact with the material:
 - Aqueous foods
 - Acidic foods
 - Alcoholic and dairy (milk) based foods
- Food contact with the material should not exceed 10 days at 40C
- The surface area/volume ratio employed in testing was 1.55cm^{-1}

This declaration is valid for the product delivered and its use as specified above. The verification of compliance was performed based on the above rules; according to which the product complies with the legal requirements subject to adherence to the stated conditions for contact with food. In case of deviations from the intended use, the user is responsible for verifying compliance and suitability.



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