

## Declaration of Compliance for a plastic final article intended to come into contact with food

### 1. Company Identification

**WATSON-MARLOW LIMITED** a company incorporated in England and Wales (registered number 02481019) having its registered office at Watson-Marlow Ltd Bickland Water Road, Falmouth, Cornwall, TR11 4RU

### 2. Description of the article

Maxthane® tubing elements

945.0032.PFT	520 LoadSure Maxthane 3.2mm Tri-Clamp Element
945.0064.PFT	520 LoadSure Maxthane 6.4mm Tri-Clamp Element
945.0096.PFT	520 LoadSure Maxthane 9.6mm Tri-Clamp Element
945.E032.K16	Maxthane 3.2mm X 1.6mm Double Segment Y-Element
945.E064.K16	Maxthane 6.4mm X 1.6mm Double Segment Y-Element
945.E080.K16	Maxthane 8.0mm X 1.6mm Double Segment Y-Element
945.E096.K16	Maxthane 9.6mm X 1.6mm Double Segment Y-Element

Fluid Contact Parts	Material Type
Tube	Thermoplastic polyester polyurethane
Loadsure connector	PVDF
Y connector	PVDF

### 3. Confirmation that those material meet the relevant requirements of Food contact regulations

The materials covered by this Declaration comply with the relevant requirements of the Framework Regulations (EC) No 1935/2004 of the European Parliament and Regulation (EC) No 10/2011 on plastic materials intended to come into contact with food.

- It is confirmed that the TPU tube materials are manufactured only with monomers, other starting substances and additives that are authorised under the Plastics Regulation.

- The PVDF connectors are manufactured with monomers which are all listed in Annex II
- It is confirmed that substances intentionally added to plastics are all subject to listings in Annex I.
- Information regarding reaction intermediates, decomposition or reaction production plastics, in order for the final user to perform further steps of the risk assessment in accordance with Article 19: **Over time, polyurethane materials may hydrolyze to their corresponding precursor diamines (for example, aromatic polyurethanes based on diphenylmethane diisocyanate may hydrolyze and produce methylene dianiline). This condition needs to be considered in any end-use application.**
- It is confirmed that the plastic article comply with their respective OML. For the assessment of the tube the following testing conditions and the OM test number OM3 according to table 3 Annex V of the Plastics Regulation have been used. The simulants used :
  - Simulant A 10% ethanol
  - Simulant B 3% acetic acid
  - Simulant D2 Olive oil

For the assessment of the connectors the following testing condition OM2 and simulants were used:

- Simulant B 3% acetic acid
  - Simulant D1 50% v/v ethanol
4. Information on substances with restrictions in Annex I or II and on intentionally added substances that are subjected to the restrictions in National Legislation (EU & EEA Countries)

	Substance	CAS	SML
PVDF	Vinylidene Fluoride	75-38-7	5 mg/kg
TPU	Confidential substance A		0.1 mg/kg
	Confidential substance B		5 mg/kg
	Confidential substance C		0.01 mg/kg

It is confirmed that the substances mentioned above comply with the appropriate restrictions, as proven by testing, if used in accordance with approved food types, time of contact, and temperature of contact as listed below.

5. Information on dual use additives:

- Substances as listed in the European legislation on additives or flavourings ((EC) no 13333/2008, 1334/2008) are not expected to be present.

6. Information related to the final use of the article.

Food Types	Exceptions	Contact time	Contact temperature	Repeated Use
All food types	No foods with high alcoholic content	Any contact conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage		yes

7. For final articles containing plastic layers behind a functional barrier:

- Not applicable.

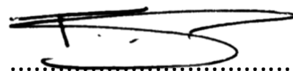
8. Sensory Testing

Sensory testing was carried out to DIN 10955 (2004-06) with tap water (2hours/ 70°C) and 6 persons in the panel.

Result: Pass no significant deterioration

9. Authorisation:

Signed for and on behalf of Watson-Marlow Limited

  
.....

Name

Tom McCormick

Position

Quality and Compliance Manager

Date

04/12/2020  
.....