

17 October 2025

RE: Declaration Of Compliance for Food Contact Materials Pumpsil Tubing

**In accordance with Article 15 and Annex IV of Regulation (EU) No. 10/2011
on plastic materials and articles intended to come into contact with food**

1. Company Identification

Operator: Watson-Marlow Limited
Registered address: Bickland Water Road, Falmouth, Cornwall, TR11 4RU,
United Kingdom
Company registration number: 02481019

2. Description of the Articles

This Declaration of Compliance applies to the following articles:

- Pumpsil Tubing 913.XXXX.XXX

Platinum-cured silicone tubing product designed for repeated use in food contact applications as defined by the legal framework specified below.

3. Applicable Regulations

The materials covered by this declaration complex with the following legal requirements:

- Regulation (EC) No. 1935/2004 — Framework Regulation on materials and articles intended to come into contact with food.
- German BfR Recommendation XV — Silicone for food contact materials.
- FDA 21 CFR 177.2600 — Rubber articles intended for repeated use.

4. Compliance Statement

When used under the conditions specified in this declaration, the overall migration levels do not exceed the legal limits defined in the aforementioned regulations. Therefore, the final articles are deemed to be in full compliance with all relevant food contact material legislation.

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5. Intended Use and Restrictions

This declaration covers intended use for contact with the following types of food:

- Aqueous foods
- Acidic foods
- Non-fatty foods
- Foods of hydrophilic character or containing low alcohol content

6. Conditions of use:

- Maximum duration of contact: 24 hours
- Maximum temperature: 40°C

7. Dual Use Additives

No dual use additives are present in the materials covered by this declaration.

8. Multilayer Articles

Final articles containing plastic layers behind a functional barrier are not applicable in this case.

9. Test Data and Results

Compliance	Test Parameter	Specification Limit	Result	Outcome
German BfR Recommendation XV	Extractable Components	≤ 0.5% w/w	Meets criteria	PASS
	Volatile Organics	≤ 0.5% w/w	Meets criteria	PASS
	Residual Peroxide	Must not test positive	Meets criteria	PASS
	Platinum Content	≤ 50 mg/kg	Meets criteria	PASS
BS EN 1230-2:2009	Taint	Not significant	Meets criteria	PASS
	Odour	Not significant	Meets criteria	PASS
FDA 21 CFR 177.2600	Water extraction	1 st extraction: <20mg/in ² 2 nd extraction: <1 mg/in ²	Meets criteria	PASS

10. Supporting Documentation


The supporting laboratory reports and all relevant analytical data are available at Watson-Marlow Limited and will be provided to competent authorities upon request.

11. Validity

This Declaration of Compliance is based on the available test results at the date of issue and reflects current manufacturing processes and material formulations. It remains valid unless product composition, manufacturing conditions, or regulatory requirements change.

12. Issue Details

Date: 17 October 2025

Issued by: 

Amie Lovatt, Validation Specialist

Department: Single-Use Technologies

Contact: Validation.Architect@wmfts.com

Company: Watson-Marlow Fluid Technology Solutions (WMFTS), incorporating the brands Watson-Marlow Pumps, Watson-Marlow Tubing, BioPure, Aflex Hose, ASEPCO, Flexicon, Bredel, and MasoSine.

13. Conclusion

This revised and formally numbered version fully aligns with the structural and content requirements of Annex IV of Regulation (EU) No. 10/2011. It is ready for use as an official Declaration of Compliance for food contact materials, fulfilling all necessary documentation and traceability criteria.