

STATEMENT PPWR **STA-UP001-26-098**

To: Whom it may concern.

The company **UNION PLASTIC**, ZA Robert, 43140 Saint-Didier-en-Velay, France, hereby declares that all its manufactured products, Medical Devices and Primary Packaging, for which it is the Legal Manufacturer, are compliant with some regulations, do not contain and have no risk of supplying some substances.

Indeed, these Medical Device and Primary Packaging are manufactured and packaged with raw materials compliant with the relevant requirements of the following non-exhaustive list:

- European Commission Regulations 10/2011 and 1935/2004 on plastic materials and articles intended to come into contact with food.
- US Code of Federal Regulations Food and Drugs Title 21 on materials used for articles or components of articles intended to come into contact with food.
- **European Regulation 2025/40 on Packaging and Packaging Waste (PPWR).**
- European Regulation 1907/2006, concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

And all their amendments.

Besides, these Medical Device and Primary Packaging and their packaging are free / have no risk of supplying:

- Bisphenol (A, B, S, F, AF...) and derivatives,
- Heavy Metals (Lead, Cadmium, Mercury, Chromium...),
- Per- and PolyfluoroAlkyl Substances (PFAS),
- Substances of Very High Concern (SVHC).



Furthermore, **UNION PLASTIC** does not use substances or any additives that may contain Bisphenols, Heavy Metals, PFAS or SVHC in its manufacturing processes. Moreover, its processes do not affect the compliance of the Medical Devices and Primary Packaging with the Regulations mentioned above.

This statement is based on the raw materials and packaging manufacturer's certificates and **UNION PLASTIC**'s internal documentation.

With kind regards,

Saint-Didier-en-Velay, June 18th 2026

Manon BRUNON

Regulatory Affairs Officer

A handwritten signature in blue ink, appearing to be 'M. Brunon', written over a faint circular stamp.

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