



EU DECLARATION OF CONFORMITY

Identification of the packaging

Packaging Identification:	Peel-pack, including Tyvek and plastic film
Type of packaging:	Sales packaging
Type of use:	Single-use
Description of packaging:	Peel-pack composed of a Tyvek layer on one side and a plastic film layer on the other, heat-sealed around the perimeter, in direct contact with the product
Intended use:	Containment and protection of the product, providing a sterile barrier system compatible with the applicable sterilization process, and enabling aseptic presentation and peel-opening at the point of use

Manufacturer

Name:	BASTOS VIEGAS, S.A.
Address:	Avenida da Fábrica 298, 4560-164 Guilhufe, Portugal

Scope, responsibility and applicable legislation

Object of the declaration:	This declaration applies to a family of packaging units sharing identical materials, design and manufacturing process, varying only in size to accommodate different quantities of units. Such variation does not affect compliance with the Regulation (EU) 2025/40.
Statement of responsibility:	The manufacturer declares, under its sole responsibility, that the packaging identified in this declaration complies with the applicable requirements of Regulation (EU) 2025/40 on packaging and packaging waste.
Applicable legislation:	The packaging complies with the applicable requirements set out in: Regulation (EU) 2025/40, of 19 December 2024, on packaging and packaging waste.

Requirements of Regulation (EU) 2025/40

Article	Requirement	Compliant	Article	Requirement	Compliant
5	Requirements for substances in packaging	Yes	6	Recyclable packaging	In progress ¹
7	Minimum recycled content in plastic packaging	In progress ¹	8	Biobased feedstock in plastic packaging	N/A
9	Compostable packaging	N/A	10	Packaging minimization	In progress ¹
11	Reusable packaging	N/A	12	Labelling of packaging	In progress ²

¹ Transitional period;

² Pending implementing act;

Conformity assessment procedure

Conformity was demonstrated in accordance with the procedure set out in Annex VII. The supporting technical documentation covers, in particular: a general description of the packaging; drawings, specifications and material composition; recyclability assessment; recycled plastic content (where applicable); and compliance with the substance restrictions.

Penafiel, Portugal, 11/08/2026

André Moreira, HSE