

EU DECLARATION OF CONFORMITY - PPWR

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Declaration n.: PPWR 21-2026

PACKAGING CODE: NBio_I_F2; NBio_O_F2

This EU Declaration of Conformity is issued in accordance with Article 39 and Annex VIII of Regulation (EU) 2025/40. The information contained herein is based on the current state of the applicable legislation and on the documentation made available by suppliers throughout the supply chain.

REFLEXX S.p.A., having its registered office at Via Passeri 2 - 46019 Viadana (MN), Italy, share capital of EUR 1,200,000 fully paid-up, VAT No. 02085450209, R.E.A. No. 223166, under its sole responsibility, in its capacity as the manufacturer of the packaging identified in this Declaration,

HEREBY DECLARES

that the packaging identified in **Annex A** complies with the applicable requirements of **Regulation (EU) 2025/40 (Packaging and Packaging Waste Regulation – PPWR)** and with any other applicable European Union legislation.

Subject of the Declaration

This Declaration applies exclusively to dispenser boxes, cartons and bags identified by their respective packaging code. It is independent of the classification of the packaged product (medical device, PPE, food contact material or any other product category).

Declared Compliance Requirements

Compliance has been assessed, where applicable, against the following requirements of Regulation (EU) 2025/40:

- limitation of the total concentration of lead (Pb), cadmium (Cd), mercury (Hg) and hexavalent chromium (Cr VI) to no more than **100 mg/kg**;
- hazardous substances present in the packaging;
- technical documentation and information received from suppliers throughout the supply chain.

Harmonised Standards and Other Technical Specifications

As of the date of issue of this Declaration, no harmonised standards relevant to the declared requirements under Regulation (EU) 2025/40 are available. Compliance is supported, where applicable, by material technical specifications, suppliers' declarations, test reports and other technical documentation.

Additional Information

- Composition of the packaging materials.

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ANNEX A – List of Covered Packaging

Packaging Code	Family	Description	Material	Packaging Type
NBio_I_F2	INNER: Packaging intended for the packing of gloves	BOX	Paper PAP21	Packaging intended for the packing and marketing of gloves
NBio_O_F2	OUTER: Logistic packaging intended for packing boxes or bags containing gloves	CARTON	Paper PAP20	Packaging intended for the packing and marketing of gloves

Place, Date

Viadana (MN), 20.07.2026

Legal Signature representative


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