

Declaration of Conformity

PDQeX Consumable Packaging

Regulation (EU) 2025/40 on Packaging and Packaging Waste

1 Declaration reference

Declaration number	EXPPWRD003
Version	1.0
Date of issue	21 August 2026

2 Manufacturer

Name	Exymes Ltd and subsidiary, Exymes NZ Ltd
Company number	15067075 (England and Wales)
Address	Alum House, 5 Alum Chine Road, Bournemouth BH4 8DT

3 Object of the declaration

Packaging group	PDQeX consumable packaging
Function	Sterile barrier packaging for PDQeX instrument tubes placed on the European Union market

The packaging comprises the following components:

- Permeable face, 60gsm medical paper
- Film backing, PET/PE film, 52-micron total thickness

Transport packaging: corrugated board outer box, in one of three formats selected by consignment size.

4 Declaration

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

The object of the declaration described above is in conformity with the applicable requirements of Regulation (EU) 2025/40 of the European Parliament and of the Council on packaging and packaging waste.

Conformity with Article 5 on substances in packaging is evidenced by supplier declarations held on file for every component, covering the combined content of lead, cadmium, mercury and hexavalent chromium against the limit of 100 mg/kg, per- and polyfluoroalkyl substances, and substances of very high concern under Regulation (EC) No 1907/2006 (REACH). The requirements of Articles 6, 7, 10 and 12 apply from the dates set in the Regulation and are addressed in the technical documentation as those dates approach.

5 Conformity assessment

Procedure	Internal production control, Module A, in accordance with Article 38 and Annex VII of Regulation (EU) 2025/40
Notified body	Not applicable. No notified body is required for internal production control.

6 References

No harmonised standards or common specifications have been adopted under Articles 36 and 37 of Regulation (EU) 2025/40 in relation to the requirements declared. Conformity is declared by reference to the following technical specifications:

- Supplier declarations of material composition and substance content held for every packaging component, addressing the combined content of lead, cadmium, mercury and hexavalent chromium, per- and polyfluoroalkyl substances, and substances of very high concern under Regulation (EC) No 1907/2006.
- Third-party analytical testing reported by suppliers where available.

7 Supporting documentation

The technical documentation supporting this declaration is held by the manufacturer and is available to market surveillance authorities on request. This declaration and the supporting technical documentation are retained for a minimum of five years from the date the packaging is placed on the market.

Technical file	EXPPWR001, PPWR Technical Documentation, Exymes Packaging, v1.0
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8 Signature

Signed for and on behalf of Exymes Ltd:

Name	Simon Wickes
Position	Group Managing Director
Date	21 August 2026
Signature	