

DECLARATION OF CONFORMITY**1. Scope of Declaration:**

This Declaration of Conformity covers all packaging materials used by PROACT Medical LTD in connection with its medical device products placed on the EU market, including primary, secondary, and tertiary/transport packaging.

2. Regulatory Basis:

This declaration is issued in accordance with the following legislation:

- Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste (PPWR), repealing Directive 94/62/EC
- Article 5 — Requirements for substances in packaging (minimization of substances of concern; heavy metal concentration limits)

3. Declaration — Article 5: Substances in Packaging:

- Substances of Concern — Minimization

PROACT Medical LTD confirms that all packaging materials used for its products have been designed and sourced such that the presence and concentration of substances of concern within the meaning of Article 5(1) of Regulation (EU) 2025/40 are reduced to a minimum. Supplier declarations and material data have been reviewed and retained as part of the technical file.

- Heavy Metals — Concentration Limit

The combined concentration of lead (Pb), cadmium (Cd), mercury (Hg), and hexavalent chromium (Cr(VI)) in the packaging materials and packaging components placed on the EU market does not exceed 100 mg/kg (100 ppm), in compliance with Article 5(2) of Regulation (EU) 2025/40.

- PFAS (Per- and Polyfluoroalkyl Substances)

The packaging materials used by PROACT Medical LTD are not intended for direct food contact. Accordingly, the PFAS-specific marketing restrictions under Article 5(3) applicable to food-contact packaging do not apply. Nevertheless, as a matter of precautionary compliance and in line with Article 5(1), PROACT Medical LTD confirms that no PFAS have been intentionally introduced into its packaging materials. Supplier confirmations to this effect are held in the technical file.

For packaging materials breakdown - See Certificate of Compliance - Packaging Materials

Date of Issue: 24-06-2026

Authorized Signatory:

Signature:



Evita Misule

QA/RA Manager/PRRC



This document has been approved by the following PROACT Medical representative(s) and has been electronically signed in accordance with the US Code of Federal Regulations Title 21 Part 11:

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