

Subject: Compliance Status & Implementation Roadmap — EU Packaging and Packaging Waste Regulation (Regulation (EU) 2025/40)

Dear Valued Customer,

STI Group is committed to complying with sustainability European Union regulatory standards. As the brand owner and legal entity placing packaged medical products on the EU market, Sterisets International B.V. (and its subsidiaries) are actively implementing the requirements of the **EU Packaging and Packaging Waste Regulation (PPWR — Regulation (EU) 2025/40)**.

This statement outlines our current verification process status, our customer communication protocols, and the following planned actions to ensure compliance with the regulation.

1. Active Verification – supplier technical documentation

August 2026 – Verification and Technical dossiers

Under Article 16 of the PPWR, component and packaging suppliers are legally obligated to provide manufacturers with technical documentation and test reports. We have formally initiated comprehensive data requests across our entire packaging supply chain (covering films, medical paperboard, inks, thermal ribbons, and cartons) to audit compliance against: Substances of Concern & Heavy Metals (Article 5), verifying that total combined Lead, Cadmium, Mercury, and Hexavalent Chromium levels do not exceed 100mg/kg.

2. Documentation Release & Customer Safeguard Protocol

August 2026 - DoCs

Because supplier data collection is actively underway across Europe during the summer period, our compliance verification is being executed and comprehends the following phases:

- **EU Declaration of Conformity (DoC) Release:** As underlying technical dossiers (Annex VII) for each product are completed and verified, Sterisets International B.V. will issue and make available the corresponding EU Declarations of Conformity (Annex VIII).
- **Immediate Customer Notification Safeguard:** If our ongoing technical audits identify any packaging material that fails to meet PPWR criteria, Sterisets will immediately notify affected customers and execute swift corrective measures.

3. Implementation Roadmap

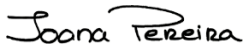
August 2028 - Harmonized Packaging Labelling

To support future compliance with the Harmonized Packaging Labelling deadline of August 2028, STI Group has established an internal implementation schedule:

In anticipation of the article 12 deadline for harmonised packaging labelling in August 2028, Sterisets is enforcing an internal purchasing cut-off date of 1 May 2027 for external packaging suppliers. The revision of the packaging criteria specifications is underway until this date to allow advance notice to be communicated to packaging suppliers, thereby ensuring compliance with the new criteria.

January 2030 – Recyclability, recycled content and minimisation

By 1 January 2030, STI Group will ensure 100% of packaging will be recyclable with a formal Recyclability Performance Grade assigned. Through proactive, advance collaboration with our supply chain partners, we will ensure full compliance with mandatory recycled content targets. Furthermore, all packaging will continue to be designed in order to reduce weight and volume to the strict minimum necessary, ensuring material efficiency without compromising product safety.

Signature: 

Function: Quality & Regulatory Affairs Director

Date: 10 -08-2026