Medical Device Packaging Compliance Checklist (EU 2025/40)

1. Scope & Applicability

- [ ] Confirm that your packaging falls under the medical device or in vitro diagnostic device categories (Regulations (EU) 2017/745 and 2017/746).
- [ ] Identify which packaging components are contact-sensitive (e.g., sterile barrier systems, primary packaging).

2. Exemptions Documentation

- [ ] Document all packaging elements that qualify for exemptions under Articles 6 and 7: - Recyclability (Article 6) - Recycled content (Article 7)
- [ ] Justify exemptions based on: - Sterility requirements - Product integrity - Regulatory safety standards

3. Design & Material Considerations

- [ ] Evaluate packaging for recyclability where exemptions do not apply.
- [ ] Investigate alternative materials that meet both safety and environmental goals.
- [ ] Avoid restricted substances (e.g., PFAS, BPA, heavy metals) unless exempted.

4. Labelling & Traceability

- [ ] Ensure packaging includes: - Required EU harmonized labels (if applicable) - Digital data carriers (e.g., QR codes) for traceability
- [ ] Maintain compliance with MDR/IVDR labelling and UDI requirements.

5. Extended Producer Responsibility (EPR)

- [ ] Register with national EPR schemes in each EU country where products are marketed.
- [ ] Report packaging volumes and types annually.
- [ ] Contribute to the cost of collection, sorting, and recycling.

6. Reuse & Refill (if applicable)

- [ ] Assess if any transport or secondary packaging can be made reusable.
- [ ] Implement reuse systems where feasible (e.g., for internal logistics).

7. Future-Proofing

- [ ] Monitor for regulatory reviews (e.g., 2035 recyclability exemption reassessment).
- [ ] Invest in R&D for sustainable packaging innovations.
- [ ] Stay updated on technical guidelines and standardization efforts.