ANNEX VIII

EU DECLARATION OF CONFORMITY

Declaration No.: DOC-PPWR-2026-001

1. Unique Identification of the Packaging

This Declaration covers the primary, secondary and tertiary packaging of the following products:

- Pectuslab GVacuum
- Pectuslab GPad
- Aleda Bar

The packaging components and technical specifications of these products are defined in Annex 1.

2. Name and Address of the Manufacturer

Tedob Prodüksiyon Sağlık ve Gıda Sanayi Ticaret Limited Şirketi

Zühtüpaşa Mah. Kördere Sok.

Serdar Apt. No:19/1

34724 Kadıköy / İstanbul / Türkiye

Tel: +90 541 427 52 52

www.pectuslab.com

3. Declaration

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

4. Object of the Declaration

This Declaration covers the complete packaging system of the following medical devices:

Pectuslab GVacuum

Pectuslab GPad

Aleda Bar

including:

- Primary packaging
- Secondary packaging
- Tertiary (transport) packaging

together with all packaging components ensuring product identification and traceability.

5. Conformity Statement

The packaging system described in Point 4 complies with all applicable requirements of:

Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on Packaging and Packaging Waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC (Packaging and Packaging Waste Regulation – PPWR).

The conformity assessment has been performed on the basis of:

- Product Technical Documentation
- Packaging Technical Specifications
- Material Technical Data Sheets
- Supplier Material Declarations

- Packaging Compliance Assessment Report
- Recyclability Assessment Report
- Recycled Content Calculation Report
- Plastic Composition Declaration

Other relevant technical documentation maintained by the manufacturer.

The manufacturer declares that the packaging covered by this Declaration fulfils all applicable PPWR requirements relevant to its design, composition and intended use.

6. References

European Union Legislation

- Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on Packaging and Packaging Waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC.

Supporting Technical Documentation

- Packaging Compliance Assessment Report
- Packaging Technical Specifications
- Material Technical Data Sheets
- Supplier Material Declarations
- Plastic Composition Declaration
- Recyclability Assessment Report
- Recycled Content Calculation Report
- Packaging Material Specifications
- Technical Documentation maintained by the Manufacturer

7. Conformity Assessment Procedure

This Declaration is issued under the applicable conformity assessment procedures established by **Regulation (EU) 2025/40**.

No Notified Body intervention is required for the packaging systems covered by this Declaration.

8. Additional Information

The plastic materials declared herein refer exclusively to packaging components, including primary, secondary and tertiary packaging.

Depending on the product configuration, the packaging materials include:

- Polyethylene (PE)
- Polylactic Acid (PLA), where applicable

Unless otherwise specified in Annex 1, no PET, PVC, PS, EPS or other plastic materials are used.

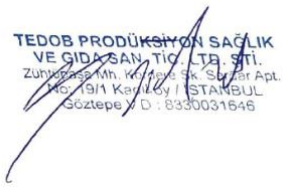
Paper-based packaging components are excluded from the plastic weight calculations.

The recycled content of each packaging component is identified in Annex 1.

This Declaration applies exclusively to packaging materials. The medical devices themselves are not considered single-use plastic products for the purposes of packaging compliance assessment.

The manufacturer further declares that:

the packaging technical documentation is maintained and kept up to date;
this Declaration is based on the latest available technical information and supplier documentation;
the Declaration will be revised whenever changes affecting packaging compliance occur.

Date of Declaration	:	03.08.2026
Place of Declaration	:	İstanbul, Türkiye
Declared by	:	Bora YÜKSEL
Signature	:	

ANNEX 1 – Packaging Components

Product	Packaging Level	Component	Material	Weight per Unit	Recycled Content
Pectuslab GVacuum	Primary	Protective Bag	Polyethylene (PE)	40 g	80%
Pectuslab GVacuum	Secondary	Box	Paper	155 g	95%
Pectuslab GVacuum	Tertiary	Stretch Film	Polyethylene (PE)	10 g	80%
Pectuslab GPad	Primary	Protective Bag	Polyethylene (PE)	60 g	80%
Pectuslab GPad	Secondary	Box	Paper	155 g	95%
Pectuslab GPad	Tertiary	Stretch Film	Polyethylene (PE)	10 g	80%
Aleda Bar	Primary	Protective Bag	Polyethylene (PE)	5 g	80%
Aleda Bar	Secondary	Box	PLA (Biodegradable Plastic)	120 g	100%
Aleda Bar	Tertiary	Stretch Film	Polyethylene (PE)	5 g	80%