

EU DECLARATION OF CONFORMITY
PURSUANT TO REGULATION (EU) 2025/40 ON PACKAGING AND PACKAGING WASTE
(PPWR) – ANNEX VIII

Document No.	HF/PPWR-DOC-VG-001	Version	A/0
Date of issue	2026-07-22	Valid from	2026-07-22

1. Name and address of the manufacturer:

Name: Cobes Industries (Hefei) Co., Ltd.

Address: No.39, Liaoyuan Road, Xincheng Development Zone, Feidong County, 231600 Hefei, PEOPLE'S REPUBLIC OF CHINA

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This declaration of conformity is issued under the sole responsibility of the manufacturer. The manufacturer is responsible for performing a regulatory watch on this EU Regulation and maintain compliance over time. The technical documentation supporting this declaration is maintained by the manufacturer and available to competent authorities upon request. This declaration and the technical documentation will be retained for 5 years (packaging is single-use)

2. Object of the declaration:

Product name:	Surgical gowns
Article Number:	992016, 992017, 992018, 992019, 992022, 992020, 992023, 992021, 992306, 992302, 992303, 992304, 992305, 992311, 992312, 992313, 992314, 992315, 992031, 992033, 992034
Description:	Single-use sterile surgical gowns packed in paper-plastic primary pouches for hospital clinical application

3. Description of the packaging

3.1. Primary packaging (Sterile Barrier System, SBS)

Type:	Paper-plastic sterilization pouch, 25cm × 37cm; affixed with self-adhesive label, 1 surgical gown packed per pouch. Paper-plastic sterilization pouch for 992016, 992017, 992018, 992019, 992022, 992020, 992023, 992021: size 25cm × 39cm, weight:12g Paper-plastic sterilization pouch for 992306, 992302, 992303, 992304, 992305, 992311, 992312, 992313, 992314, 992315 992031, 992033, 992034: size 25cm × 37cm, weight:12g Self-adhesive label: size 10x4cm, weight:0.4g
Material:	60gsm Medical dialysis paper laminated with 52μm transparent multi-layer medical film (polyethylene (PE) + polyethylene terephthalate (PET))

3.2. Secondary packaging (Grouped collecting packaging)

Type:	Transparent PE bag, used to bundle multiple primary SBS pouches; 992016: 20pcs/bag; 992017: 20pcs/bag; 992018: 20pcs/bag; 992019: 22pcs/bag; 992022: 20pcs/bag; 992020: 20pcs/bag; 992023: 18pcs/bag; 992021: 18pcs/bag; 992306: 36pcs/bag; 992302: 36pcs/bag; 992303: 36pcs/bag; 992304: 32pcs/bag; 992305: 30pcs/bag; 992311: 32pcs/bag; 992312: 32pcs/bag; 992313: 28pcs/bag; 992314: 24pcs/bag; 992315: 22pcs/bag; 992031: 24pcs/bag; 992033: 22pcs/bag; 992034: 20pcs/bag Transparent PE bag: size 110x90cm, thickness 0.035mm, weight:67.32g
Material:	Polyethylene (PE) plastic film

3.3. Tertiary packaging (outer carton)

Type:	Non-printed outer carton; 1 full secondary PE bag loaded per carton; one rigid cardboard sheet placed above goods inside carton; sealed with BOPP carton-sealing pressure-sensitive adhesive tape; two self-adhesive labels and 1 sterilization indicator label affixed on carton surface.
Material:	corrugated cardboard (paper-based material, double wall 5-layer corrugated board) Non-printed outer carton: 992016/992306/992302/992303/992304/992305/992311/992312/992313/992314/992315 Non-printed outer carton: size 60 ×40 ×24cm, weight:1047g; 992017/992018/992022/992020//992023/992021 Non-printed outer carton: size 60 ×40 ×26cm, weight: 1050g; 992019 Non-printed outer carton: size 60 ×40 ×30cm, weight:1146; 992031/992033/992034 Non-printed outer carton: size 60 ×40 ×28cm, weight: 1086; Rigid cardboard sheet: size 12 inch × 6 inch, weight:20g; BOPP carton-sealing pressure-sensitive adhesive tape: size 6cm width, weight:9g/bag; Self-adhesive labels: size 21 ×14.8cm, weight:3.2g; Sterilization indicator label :size Diameter: 3 cm, weight: 00721g

4. Applicable Union legislation

The packaging described above complies with the requirements of:

Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on Packaging and Packaging Waste (PPWR)

5. Harmonised standards applied

- EN 13427 – Requirements for the use of European Standards in the field of packaging and packaging waste
- EN 13428 – Packaging – Requirements specific to manufacturing and composition – Prevention by source reduction
- EN 13430 – Packaging – Requirements for packaging recoverable by material recycling

6. Conformity statement

This declaration of conformity is issued under the sole responsibility of the Manufacturer (COBES INDUSTRIES (BAGO) COMPANY LIMITED). The object of the declaration described above is in conformity with the relevant Union harmonization legislation – Regulation (EU) 2025/40 (PPWR).

Art. 5: Substances of concern in packaging	The sum of the concentrations of lead, cadmium, mercury and
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	hexavalent chromium do not exceed 100 mg/kg. The substances comply with Regulation (EC) No 1907/2006 (REACH).
Art. 6: Recyclability	The packaging is recyclable.
Art. 7: Recycled content (plastics)	These articles are not yet mandatory. They depend on delegated acts to be adopted by the European Commission by 1 January 2028. This template will require updating once those acts are published.
Art. 8: Compostability requirements	
Art. 9: Reusability requirements	
Art. 10: Packaging minimization	
Art. 11: Packaging format restrictions	
Art. 12: Labelling requirements	

Li Zhao hong

Hefei, 2026.07.22

Place and date

Li Zhao hong, PRRC

Signature and position