

EU Declaration of Conformity

Manufacturer: **Cobes Industries (Hefei) Co., Ltd.**
Address: No.39 Liaoyuan Road, Xincheng Development Zone,
Feidong County, 231600 Hefei, PEOPLE'S REPUBLIC OF CHINA
CN-MF-000012364

European Representative: **Emergo Europe B.V.**
Address: Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.
SRN: NL-AR-000000116

Product Name: Surgical Gowns

Product Models: Please refer to the attachment for product list

Basic UDI-DI: 69562886AA0002FG, 69562886AA0003FJ

EMDN Code: T0204

Notified Body: TÜV SÜD Product Service GmbH
Add: Ridlerstraße 65, 80339 MÜNCHEN, Germany

NB Identification number: 0123

CE Certificate Number: G21 059012 0020 Rev. 01

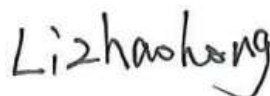
Classification: Class Is, Rule 1 according to Annex VIII of Regulation EU 2017/745

Conformity Assessment Route: Annex XI, Part A according to Regulation EU 2017/745

The device covered by the present declaration is in conformity with Regulation EU 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer **Cobes Industries (Hefei) Co., Ltd.**

References to harmonized standards and common specifications used and for which conformity is declared: EN ISO13485: 2016/A11: 2021, EN ISO 14971: 2019/ A11: 2021, EN ISO 15223-1: 2021, EN 13795-1: 2019, ASTM F1980: 2021, EN 62366-1: 2015/A1: 2020, EN ISO 20417: 2021, EN ISO 10993-1: 2020, EN ISO 10993-5: 2009, EN ISO 10993-7: 2008/A1: 2022, ISO 10993-10: 2021, EN ISO 10993-23: 2021, EN ISO 10993-12: 2021.

Signature: 

Place, date of issue: Hefei, Feb 06, 2025

Name: Zhaohong Li

Position: PRRC

Revision History

Date	Revision Content	Modified by
2024/06/14	Initial	Hanfei Zhou
2025/02/06	Update the CE certificate number	Hanfei Zhou

Attachment:

Product code	Product name	Additional info	BASIC UDI-DI
992306	Foliodress® Gown Blue Standard	Size M	69562886AA0002FG
992302	Foliodress® Gown Blue Standard	Size L	69562886AA0002FG
992303	Foliodress® Gown Blue Standard	Size XL	69562886AA0002FG
992304	Foliodress® Gown Blue Standard	Size XXL	69562886AA0002FG
992305	Foliodress® Gown Blue Standard	Size XXL extra-long 158cm	69562886AA0002FG
992311	Foliodress® Gown Blue Reinforced	Size M	69562886AA0003FJ
992312	Foliodress® Gown Blue Reinforced	Size L	69562886AA0003FJ
992313	Foliodress® Gown Blue Reinforced	Size XL	69562886AA0003FJ
992314	Foliodress® Gown Blue Reinforced	Size XXL	69562886AA0003FJ
992315	Foliodress® Gown Blue Reinforced	Size XXL extra-long 158cm	69562886AA0003FJ