

EU Declaration of Conformity

Manufacturer: **COBES INDUSTRIES (BAGO) COMPANY LIMITED**
Address: No.13, Internal Industrial Zone, Bago Township, Bago Region,
Myanmar
SRN: MM-MF-000012366

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: 883000024AA0002HJ, 883000024AA0003HL

EMDN Code: T0204

Notified Body: SGS Belgium NV
Add: Noorderlaan 87 BE-2030 Antwerpen, Belgium

NB Identification number: 1639

CE Certificate Number: HK25/00000114

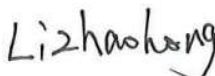
Classification: Class Is, Rule 1 according to Annex VIII of Regulation EU 2017/745

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, Jun 16, 2025

Name: Zhaohong Li

Position: PRRC

Revision History

Date	Revision Content	Modified by
2025/02/06	Initial	Hanfei Zhou
2025/06/16	Updated the CE Certificate Number	Hanfei Zhou

Attachment:

Product code	Product name	Additional info	BASIC UDI-DI
992401	Foliodress® Gown Blue Standard	Size M	883000024AA0002HJ
992402	Foliodress® Gown Blue Standard	Size L	883000024AA0002HJ
992403	Foliodress® Gown Blue Standard	Size XL	883000024AA0002HJ
992404	Foliodress® Gown Blue Standard	Size XXL	883000024AA0002HJ
992405	Foliodress® Gown Blue Standard	Size XXLL 158cm	883000024AA0002HJ
992411	Foliodress® Gown Blue Reinforced	Size M	883000024AA0003HL
992412	Foliodress® Gown Blue Reinforced	Size L	883000024AA0003HL
992413	Foliodress® Gown Blue Reinforced	Size XL	883000024AA0003HL
992414	Foliodress® Gown Blue Reinforced	Size XXL	883000024AA0003HL
992415	Foliodress® Gown Blue Reinforced	Size XXLL 158cm	883000024AA0003HL