

EU Declaration of Conformity

Manufacturer: Cobes Industries (Hefei) Co., Ltd.
Address: NO.39 Liaoyuan Road Xincheng Development Zone, Feidong County, Hefei, 231600 the 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

Intended Purpose: The surgical gowns are specially designed for the medical staff entering the operating room for operation. During surgery, the surgical gowns are worn on the medical staff to prevent the transmission of infectious agents between patients and medical staff during the operation and other invasive examinations.

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. 00

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, 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: *Li Zhaohong*

Place, date of issue: Hefei, April 13, 2024

Name: Zhaohong Li

Position: PRRC

Revision History

Date	Revision Content	Modified by
2023/11/16	Initial	Hanfei Zhou
2024/2/28	Update the attachment for product list	Hanfei Zhou
2024/4/13	Update the attachment for product list	Hanfei Zhou

Attachment:

Product Name	Product Code	BASIC UDI-D
Foliodress® Gown Soft Standard L	992016	69562886AA0002FG
Foliodress® Gown Soft Standard XL	992017	69562886AA0002FG
Foliodress® Gown Soft Standard XL extra-wide	992018	69562886AA0002FG
Foliodress® Gown Soft Standard XXL	992019	69562886AA0002FG
Foliodress® Gown Soft Reinforced L	992022	69562886AA0003FJ
Foliodress® Gown Soft Reinforced XL	992020	69562886AA0003FJ
Foliodress® Gown Soft Reinforced XXL	992021	69562886AA0003FJ
Foliodress® Gown Soft Reinforced XL extra-wide	992023	69562886AA0003FJ