



# DECLARATION OF CONFORMITY

## ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

### EU Representative

**SUNGO Europe B.V.**  
Fascinatio Boulevard 522, Unit 1.7, 2909VA  
Capelle aan den IJssel, The Netherlands  
SRN: NL-AR-000000247

### Conformity Assessment

**Conformity Assessment Procedure**  
Annex II+III of Regulation (EU) 2017/745

### Applicable Standards

EN ISO 14971: 2019 EN ISO 15223-1: 2021  
EN ISO 20417: 2021 EN ISO 10993-1: 2020  
EN ISO 10993-5: 2009 EN ISO 10993-10: 2013

### Intended Use

A non-woven medical gown creates a barrier that minimizes the direct transfer of infectious agents and bacteria to the surgical wound, which limits the possibility of wound infection and reduces the risk of post-operative complications, or generally reduces the possibility of transfer of pathogenic microorganisms during procedures. A non-woven medical gown is a barrier medical device designed to provide a clean barrier, when there is no need to use sterile surgical gowns - in emergency departments, hospital emergency departments, surgical departments, and during minor surgical procedures. The device can also be used in other clinical hazardous environments, such as emergency rooms, delivery areas and intensive care units, or in the care of immunocompromised patients. For use by qualified personnel (professional users). Single-use product, not sterile.

### Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-T0299-03.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

### Manufacturer

**Unimax Medical Products Co., Ltd.**  
Special No.1 Liansai Road, Changshangkou Town,  
433024 Xiantao City, Hubei Province, P. R. China  
SRN:CN-MF-000017381

### Product Information

**Name:** Disposable Clothing

**Model:** Non-woven medical gown

W267100130\_0028, W267100140\_0028, W267100150\_0028,  
W267100160\_0028, W267200130\_0028, W267200140\_0028,  
W267200150\_0028, W267200160\_0028  
W267100230\_0028, W267100240\_0028, W267100250\_0028,  
W267100260\_0028, W267200230\_0028, W267200240\_0028,  
W267200250\_0028, W267200260\_0028

**EMDN:** T0299

**Basic UDI-DI:** 697349085UMDCT2

**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

### Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

For and on behalf of  
**UNIMAX MEDICAL PRODUCTS CO., LTD.**  
聯賽醫用產品(湖北)有限公司

Signature: Ning Haibo Date: 2023/10/06

Authorized Signature(s)

Position: General Manager Place: Hubei/China